DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 406, 407, 408, 410, 423, 431, and 435

[CMS–4199–F]

RIN 0938–AU85

Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule implements certain provisions of the Consolidated Appropriations Act, 2021 (CAA). Additionally, we are proposing to delete references to specific Medicare forms from the text of existing regulations at §§ 406.7 and 407.11 in order to provide greater administrative flexibility. Finally, this final rule updates the various federal regulations that affect a State's payment of Medicare Part A and B premiums for beneficiaries enrolled in the Medicare Savings Programs and other Medicaid eligibility groups.

DATES: This final rule is effective on January 1, 2023, except for the addition of § 407.47(f) at instruction 21, which is effective on January 1, 2024.

FOR FURTHER INFORMATION CONTACT:

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Carla Patterson, (410) 786–8911—For inquiries related to the Medicare enrollment form.

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SUPPLEMENTARY INFORMATION:

I. Summary

A. Beneficiary Enrollment Simplification in Medicare Parts A and B—Background and Proposal Summary

Medicare is a Federal program to provide health insurance for people age 65 and older, and those under 65 with certain disabilities or End-Stage Renal Disease (ESRD). Medicare consists of four distinct parts, commonly referred to as Medicare Parts A, B, C and D. Medicare Part A, sometimes referred to as hospital insurance (HI), covers inpatient hospital services, skilled nursing care, hospice care, and some home health services. Individuals must meet certain conditions to be entitled to Part A. Medicare Part B, or supplementary medical insurance (SMI), is an optional benefit that helps cover medically necessary services and supplies like physicians' services, durable medical equipment (DME), outpatient care, and other medical services that Part A does not cover, including many preventive services. Together, Medicare Parts A and B comprise ''original'' or ''traditional'' Medicare. Most beneficiaries are automatically enrolled in Part A and Part B by the Social Security Administration (SSA) or the Railroad Retirement Board (RRB) when they turn 65 because they are already receiving social security or RRB retirement benefits. In addition, if an individual has been receiving Social Security or Railroad Retirement Disability benefits for 24 months, they will automatically be enrolled by SSA or the Railroad Retirement Board in Medicare Parts A and B.

The first opportunity individuals have to enroll in Part B is during their initial enrollment period (IEP). The IEP is a 7-month period that usually begins 3 months before the month in which an eligible individual turns 65 and ends 3 months after the first month of eligibility. The next opportunity for eligible individuals who do not enroll in Part B during their IEP to enroll in Part B, if they choose to do so, is in the general enrollment period (GEP) which runs from January 1st through March 31st each year. Currently, an individual's entitlement (coverage period effective date) under Part B depends on the enrollment period and the month in which the individual enrolls, according to the requirements in sections 1837 and 1838 of the Social Security Act (the Act).

For those who enroll in Medicare Part B during any of the first 3 months of their IEP, coverage is effective the first month they become eligible for Medicare (such as age 65 or the 25th month of entitlement to monthly Social Security or railroad retirement benefits based on disability). However, for those who enroll in any of the last 4 months of their IEP, their coverage becomes effective after their month of enrollment, with the effective date of coverage varying depending on the month in which they enroll. For eligible individuals who enroll during the GEP, coverage is effective the July 1 following the month in which the individual enrolls.

Section 120 of the Consolidated Appropriations Act, 2021 (CAA), Public Law (Pub. L.) 116–260, Division CC, title I, section 120 (December 27, 2020), modified the requirements in section 1838 of the Act, pertaining to individuals enrolling in Part B after not being automatically enrolled, or who are re-enrolling in Part B after disenrollment. Specifically, the CAA revised sections 1838(a)(2)(C), 1838(a)(3)(A), and 1838(a)(2)(D) of the Act to provide that for individuals who become eligible for Medicare on or after January 1, 2023, and enroll in Part B during the last 3 months of their IEP, entitlement would begin the first day of the month following the month in which they enroll. We proposed conforming changes to our regulations at 42 CFR part 407 to implement these Part B changes. In addition, while the statutory provisions of section 120 of the CAA primarily affect individuals enrolling in Part B, those changes will also affect the requirements applicable to the limited number of individuals enrolling in Part A who are not entitled to premium-free Part A. We proposed conforming modifications to our regulations at 42 CFR part 406 to reflect those Part A changes.

Additionally, section 120 of the CAA established new section 1837(m) of the Act, which provides authority for the Secretary of the Department of Health and Human Services (HHS) (the Secretary) to establish special enrollment periods (SEPs) for individuals who are eligible to enroll in Medicare and meet such exceptional conditions as the Secretary may provide, effective January 1, 2023. Corresponding changes in section 1838(g) of the Act provides the Secretary the discretion to determine the effective date of entitlement for individuals who enroll under an SEP for exceptional conditions, and amendments to section 1839(b) of the Act exempt individuals enrolling under such an SEP from being subject to a late enrollment penalty (LEP). We proposed to establish several SEPs for exceptional conditions that would be incorporated

in our regulations under 42 CFR parts 406 and 407.

B. Extended Coverage of Immunosuppressive Drugs for Certain Kidney Transplant Patients—Background and Proposal Summary

ESRD is a medical condition in which a person's kidneys cease functioning permanently, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life. A kidney transplant is ultimately considered the best treatment for ESRD. Section 226A of the Act includes a provision that enables certain individuals diagnosed with ESRD to be entitled to Medicare, regardless of age. If an individual with ESRD applies for Medicare and is entitled to Medicare Part A and eligible for Part B benefits, Medicare provides coverage for all covered medical services, not only those related to the kidney failure condition. When an individual receives a kidney transplant, Medicare coverage extends for 36 months after the month in which the individual receives the transplant. Currently, after the 36th month, Medicare coverage ends unless the individual is eligible for Medicare on another basis, such as age or disability. Medicare Part B covers medical and other health services including, as specified in section 1861(s)(2)(J) of the Act, prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which Medicare payment is made. Kidney transplant recipients must take immunosuppressive drugs to help prevent their immune systems from rejecting the transplanted kidney. If a transplanted kidney is rejected, the individual would revert to ESRD status and again need dialysis treatment or another transplant.

Under current law, Medicare Part B beneficiaries have coverage for such immunosuppressive drug therapy for as long as they remain eligible for and enrolled in Medicare Part B. However, section 226A(b)(2) of the Act currently requires that entitlement to Medicare Part A and eligibility to enroll under Part B for ESRD beneficiaries ends with the 36th month after the month in which the individual receives a kidney transplant (see also 42 CFR 406.13(f)(2)). Section 402 of the CAA amended sections 226A(b)(2) (and made conforming changes to sections 1836, 1837, 1838, 1839, 1844, 1860D–1, 1902, and 1905 of the Act) to make certain individuals eligible for enrollment under Medicare Part B solely for the purpose of coverage of immunosuppressive drugs described in section 1861(s)(2)(J) of the Act. Effective January 1, 2023, this provision allows certain individuals whose Medicare entitlement based on ESRD would otherwise end after a kidney transplant to continue enrollment under Medicare Part B only for the coverage of immunosuppressive drugs described in section 1861(s)(2)(J) of the Act. These individuals would not receive Medicare coverage for any other items or services (under either Part A or Part B), and would only be eligible for immunosuppressive drug coverage under Part B if they are not enrolled in certain other types of coverage, as described in ''Eligibility for the Part B–ID Benefit'' (section II.B.2.b. of this final rule). Section 402 of the CAA also amended the Medicare Savings Programs (MSPs) under sections 1905(p)(1)(A) and 1902(a)(10)(E) of the Act to pay the Part B premiums and in some cases the costs of the Part B deductible and coinsurance for immunosuppressive drug coverage for certain low-income individuals.

C. Simplifying Regulations Related to Medicare Enrollment Forms—Background and Proposal Summary

Individuals who receive monthly Social Security or railroad retirement benefits at age 65 or have been entitled to monthly Social Security or railroad retirement benefits based on disability benefits for more than 24 months, are automatically entitled to Part A and do not have to file a separate application in order to enroll in premium-free Part A. These individuals are automatically enrolled (auto-enrolled) by the Social Security Administration or the Railroad Retirement Board into Part A when they reach age 65 or their 25th month of entitlement to Social Security or railroad retirement benefits based on disability. Individuals who become eligible for premium-free Medicare but who are not auto-enrolled, either because they have delayed receiving Social Security or railroad retirement benefits, or are not eligible for such benefits but are otherwise eligible to receive premium-free Medicare part A based on paying the Medicare payroll tax, must file a separate application to enroll in Medicare. Individuals who decide to collect Social Security benefits after they reach age 65, and thus did not get auto-enrolled in Medicare by virtue of receiving Social Security benefits, may use their application for Social Security benefits, as defined in 42 CFR 400.200, to apply for Medicare if they are eligible for Part A at that time. Individuals may also separately request enrollment in Part B by answering the Part B enrollment questions on an application for monthly Social Security retirement or spousal benefits. As an alternative, individuals may enroll in Part B by signing a simple statement of request, if they are eligible to enroll at that time.

Currently, there are a total of seven enrollment forms for traditional Medicare—two enrollment forms for Part A and five enrollment forms for Part B, in §§ 406.7 and 407.11, respectively. Medicare enrollment forms are available to individuals via mail from CMS or SSA, downloadable via the CMS [1] and SSA [2] websites, or in person at SSA field offices. CMS and SSA periodically review the enrollment forms to determine if updates are necessary to comply with statutory, regulatory, or operational changes. Our regulations currently identify each form by name and provide a brief description of its uses.

We proposed to remove references to individual enrollment forms from our regulations, including their titles and brief descriptions, to provide greater administrative flexibility in updating, adding, or removing forms in the future. We also proposed to make technical edits to the text at § 406.7 to state that an individual who files an application for monthly Social Security cash benefits as defined in § 400.200 also applies for Medicare entitlement if he or she is eligible for hospital insurance at that time. Current regulations do not define Social Security cash benefits. We proposed to provide more clarity on when a Social Security application also applies for Medicare entitlement to Part A.

D. Modernizing State Payment of Medicare Premiums—Background and Proposal Summary

Since the implementation of the original Medicare program in 1966, section 1843 of the Act has provided States the option to enter into an ''agreement'' with the Federal government under which a State commits to enrolling certain Medicare-eligible Medicaid beneficiaries into Medicare Part B with the State paying the Part B premiums on their behalf. Section 1903(a)(1) and (b) of the Act authorize federal financial participation (FFP) for such State payment of Part B premiums for certain dually eligible individuals. We have historically referred to this process as ''State buy-in.'' All 50 States and the District of

[1] *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List.*

[2] *https://www.ssa.gov/forms/.*

Columbia have buy-in agreements for Part B [3] with the Secretary.

States pay Medicare Part B premiums for approximately 10 million individuals and Part A premiums for approximately 700,000 individuals each year who are not entitled to Part A without a premium. For an individual who is eligible for but not yet enrolled in Medicare, State buy-in serves to both enroll the individual in Medicare and enable the Federal Government to bill the State for the new beneficiary's Medicare premiums. For an individual who is already enrolled in Medicare, State buy-ins enable the Federal Government to bill the State for the individual's Medicare premiums and stop collecting the premiums through deductions from the beneficiary's monthly Social Security (Old Age Insurance or Disability benefits or Supplemental Security Income), Railroad Retirement Board (RRB), or Office of Personnel Management (OPM) benefits, or through CMS direct billing.

The impact of State buy-in is significant for many beneficiaries. Low-income individuals who receive assistance with Medicare premiums save critical funds to use for other necessities, including food and housing. Upon State buy-in, individuals who were paying the Medicare premiums through deductions from their Social Security benefits see a notable increase in their monthly social security checks (the standard Part B premium will be $164.90 per month in 2023), and individuals eligible but not enrolled in Medicare are able to enroll in the program and access Medicare services.

We proposed several technical updates to the regulations pertaining to State buy-in that would better align them with federal statute, policy and operations that have evolved over time. We also proposed revising the regulations to provide that approved State plan provisions governing the buy-in process constitute a State's buy-in agreement and limiting retroactive Medicare Part B premium liability for States for full-benefit dually eligible beneficiaries.

[3] Thirty-seven States (including the District of Columbia) also have buy-in agreements for Part A.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. Proposals for Beneficiary Enrollment Simplification (§§ 406.21, 406.22, 406.27, 406.33, 406.34, 407.23, 407.25, and 408.24)

1. Effective Dates of Entitlement

While the majority of individuals are automatically enrolled in Medicare Parts A and B upon reaching age 65 or when they have been entitled to monthly Social Security or railroad retirement benefits based on disability for more than 24 months, certain individuals are required to take active steps to enroll. Specifically, individuals who are eligible for, but not receiving, monthly Social Security benefits under section 202 of the Act or qualified RRB benefits when they turn 65, are not auto-enrolled because they have elected not to start receiving their Social Security or RRB benefits and have not filed an application for Social Security or RRB benefits and must take separate action to apply for Medicare. Certain individuals who are entitled to premium free Part A through government employment, but are not eligible for Social Security or RRB benefits also have to take action to apply for Medicare. Individuals may apply for Part A at any time, but can only apply for Part B during a specific enrollment period (IEP, GEP, or SEP). Further, under section 1818 of the Act, certain individuals who are not otherwise entitled to Part A but meet certain requirements, are eligible to enroll in Part A. These individuals are required to pay monthly premiums under section 1818(d) of the Act, and this benefit is frequently referred to as ''premium Part A.'' These individuals are required to take active steps to enroll in premium Part A and Part B.

- *IEP:* The period during which individuals eligible for premium Part A are entitled to receive benefits under Medicare, also known as the coverage period, can vary depending on when the individual enrolls. The first opportunity individuals have to enroll in Part B is during their IEP. Section 1837(d) of the Act defines the IEP for most individuals who become eligible for Medicare on or after March 1, 1966. For individuals age 65 and older enrolling in Part A, the IEP is the 7-month period that begins 3 months before the month in which the individual is first eligible for Medicare and ends 3 months after the first month of eligibility.
- *Deemed IEP:* Section 1837(d) of the Act also defines what is commonly referred to as the ''deemed IEP.'' When an individual fails to enroll during their IEP because of a belief, based on documentary evidence, that he or she had not yet attained age 65, section 1837(d) of the Act requires the Secretary to establish an IEP for such individual based on the time shown in such documentary evidence of the individual attaining age 65. Such individuals are considered ''deemed'' to have enrolled for purposes of section 1838(a)(3) of the Act, and these individuals are subject to entitlement periods consistent with those for individuals not subject to a deemed initial enrollment period under 42 CFR 407.14.
- *GEP:* Eligible individuals who do not enroll in Part B during their IEP or deemed IEP, or who disenroll from Part B and wish to re-enroll, must generally do so during the GEP. The GEP is established under section 1837(e) of the Act, and is the period beginning on January 1 and ending on March 31 of each year.

Section 1838(a) of the Act establishes the beginning of entitlement for Part B for individuals who enroll in their IEP or GEP. According to the current requirements established under sections 1838(a)(2)(A) and 1838(a)(3)(A) of the Act individuals who become eligible to enroll in Medicare under section 1836(a) of the Act before January 1, 2023, and enroll:

- During the first 3 months of their IEP or deemed IEP, their entitlement would begin on the first day of the month they turn 65.
- The month in which they become eligible, sections 1838(a)(2)(B)(i) and 1838(a)(3)(B)(i) of the Act currently specify that their entitlement begins with the first day of the month following the month in which they enroll.
- The month in which they satisfy the requirements of section 1836(a) of the Act, their entitlement would begin with the first day of the second month after the month in which they enroll under sections 1838(a)(2)(B)(ii) and 1838(a)(3)(B)(i) of the Act.
- During the last 2 months of their IEP or deemed IEP, their entitlement under Medicare would be effective beginning with the first day of the third month after the month in which he or she enrolls according to sections 1838(a)(2)(B)(iii) and 1838(a)(3)(B)(i) of the Act.
- Under the GEP sections 1838(a)(2)(D)(i) and 1838(a)(3)(B)(i) provide that their entitlement would begin with the first of July following their enrollment.

Section 120(a)(1) of the CAA revised the entitlement periods for individuals who enroll in Medicare Part B in the last 3 months of their IEP, deemed IEP, or

during the GEP, beginning January 1, 2023. Specifically, the CAA modified section 1838 of the Act such that revised section 1838(a)(2)(C) and (a)(3)(B)(ii) of the Act provide that for a Medicare eligible individual who satisfies the requirements of section 1836(a) of the Act (*i.e.,* is entitled to Part A, or, is age 65, a resident of the United States, and is either (A) a citizen or (B) an alien lawfully admitted for permanent residence who has resided in the United States continuously during the 5 years immediately preceding the month in which he applies for enrollment), in a month beginning on or after January 1, 2023, and who enrolls in the month in which they satisfy those requirements, or in any subsequent month of their IEP, the individual's entitlement would begin with the first day of the month following the month of enrollment. The CAA also revised sections 1838(a)(2)(D)(ii) and 1838(a)(3)(B)(ii) of the Act to provide that for individuals who enroll during the GEP in a month beginning on or after January 1, 2023, their entitlement would begin with the first day of the month following the month in which they enroll. An example of the current entitlement dates compared to the revisions made by the CAA is provided in the table:

Enrolls in IEP:	Prior to 1/1/23—Entitlement begins on:	On or After 1/1/23—Entitlement begins on:
January	April 1 (month eligibility requirements first met)	April 1 (month eligibility requirements first met).
February	April 1	April 1.
March	April 1	April 1.
April	May 1 (month following month of enrollment)	May 1.
May	July 1 (second month after month of enrollment)	June 1.
June	September 1 (third month after month of enrollment)	July 1.
July	October 1 (third month after month of enrollment)	August 1.
January	July 1	February.
February	July 1	March.
March	July 1	April.

As shown in the chart, the changes made to section 1838(a) of the Act according to section 120 of the CAA directly affect the requirements for individuals enrolling in Part B. However, these changes will also impact certain individuals enrolling in Part A. Section 1818(c) of the Act specifically requires in part that the provisions of section 1838 of the Act apply to individuals enrolling in premium Part A for purposes of determining the period of enrollment and other aspects of coverage. In light of this statute, the revised entitlement periods established in section 1838(a) of the Act will also apply to premium Part A enrollees.

To implement the changes to 1838(a) of the Act, we proposed to revise language in both 42 CFR part 406 (for premium Part A) and 42 CFR part 407 (for Part B). Specifically, we proposed the following to reflect changes related to the start of entitlement for premium Part A IEP enrollments as summarized:

- Revised § 406.22(a) would apply the existing requirements governing the entitlement period for individuals who are age 65 or older before January 1, 2023 who enroll in premium Part A during their IEP.
- New § 406.22(b) would lay out the entitlement dates for individuals who attained age 65 on or after January 1, 2023, and who enroll during their IEP, including a deemed IEP.
- Newly redesignated and revised § 406.22(c) would apply the existing entitlement date requirements for individuals under age 65 who became eligible for Medicare prior to January 1, 2023.
- New § 406.22(d) would set out the start dates for entitlement for individuals under age 65 who enroll in premium Part A on or after January 1, 2023.

We also proposed the following to reflect changes related to the start of entitlement for individuals enrolling in Part B during their IEP:

- Revised § 407.25(a)(1) applied the existing entitlement date requirements to individuals who first satisfy the Part B eligibility requirements before January 1, 2023 and enroll during their IEP or deemed IEP.
- Revised § 407.25(a)(2) applied new entitlement dates requirements to individuals who first satisfy the Part B eligibility requirements on or after January 1, 2023.

Section 120(a)(1)(A) of the CAA also modified section 1838(a)(2) of the Act, to address the beginning of the entitlement for individuals enrolling during their GEP according to 1837(e) of the Act. We proposed the following changes to reflect the updates in entitlement for individuals enrolling during the GEP:

- Revised § 406.21(c)(3) reflected the revised entitlement periods for individuals who enroll or reenroll during a GEP.
- Revised § 407.25(b)(1) specified that for individuals enrolling or reenrolling in Part B during a GEP before January 1, 2023, the current requirements governing the entitlement date would continue to apply.
- New § 407.25(b)(3) specified that for individuals who enroll or reenroll in Part B during a GEP on or after January 1, 2023, entitlement would begin the first day of the month following the month of enrollment.

We received a large number of comments related to our proposals for effective dates of entitlements. The comments on those proposals and our responses follow:

Comment: All commenters on this proposal expressed support for the proposed changes to the effective dates. Many of the comments referred to the positive outcomes that will result from the proposal. The commenters expressed that the proposed changes to the effective dates will alleviate much of the confusion surrounding Medicare enrollment. Commenters also noted that the changes will ease the stress individuals face with regard to waiting months for their enrollment to start and allow them to receive coverage in a timelier manner. A few commenters noted that outreach and education materials, including translated materials, will need to be updated to reflect these changes.

Response: We appreciate the overwhelming support for our proposal and thank those that took the time to give us feedback. We are in agreement with commenters that these changes will simplify the enrollment process and will result in a more efficient and positive experience for those seeking to enroll in Medicare. We will also take measures to update publications, training materials, and other outreach materials, as well as work with Medicare stakeholders, to update educational and outreach materials with the new changes. This includes that translation of materials into multiple different languages as needed.

Comment: A commenter had a concern in regards to when the proposed changes would be implemented. Specifically, they stated that the Medicare Part A changes would be effective in 2023 and the Medicare Part B proposed changes would be effective in 2022, and they recommended that these proposals be implemented simultaneously.

Response: We appreciate the feedback from the commenter and clarify that, as proposed, these changes for both Medicare Parts A and B are effective for enrollments on or after January 1, 2023. This timeframe is also articulated in Section 120 of the CAA.

Comment: Another commenter expressed concern for individuals that may wish to delay their coverage to begin after retirement and provided an example of a teacher that becomes Medicare eligible in the fall but wishes to delay enrollment until retirement in May. The commenter requested an arrangement be made in this regulation to allow for individuals to delay enrollment until retirement.

Response: When an individual is determining their plan for enrollment and considering when they want their Medicare coverage to become effective, they should keep in mind all enrollment opportunities available, such as the various enrollment periods and the group health plan (GHP) SEP (Sections 1837(i)(1) through (3)), which has different rules for when coverage becomes effective. The GHP SEP allows individuals to enroll at a later date as long as they were covered under insurance through their employer. Those wishing for their coverage to begin after retirement may be eligible and could consider this option.

Comment: A few commenters expressed support for the proposed changes but provided feedback on areas that were not addressed in the proposed rule. A commenter believed that the 2-year waiting period to receive Medicare while receiving Social Security Disability Insurance (SSDI) benefits is too long and that SSDI beneficiaries seeking to enroll in Medicaid should not have to adhere to any income restrictions or waiting periods. Another commenter suggested that we include more detailed language related to beneficiary coverage through telehealth. Lastly, a commenter suggested that we update the SEP for Medicare Advantage Prescription Drug Plan or stand-alone Part D Prescription Drug Plan during the Part B GEP (located at § 423.38(c)(16)) to align with the changes in the proposed rule.

Response: We thank the commenters for their support of the proposed changes but note that these areas are outside of the scope of this rulemaking.

We appreciate the feedback that we received on the entitlement date changes from commenters. Based on analysis of the public comments, we will be finalizing the proposals related to entitlement effective dates as proposed.

2. Special Enrollment Periods for Exceptional Conditions

Under normal conditions, individuals who want to enroll in premium Part A, Part B, or both must submit a timely enrollment request during their IEP, the GEP, or an existing SEP for which they are eligible. Those who fail to enroll during their IEP may face an LEP [4] and a potential gap in coverage. Prior to the enactment of the CAA, CMS did not have broad authority to create SEPs based on exceptional conditions for enrollees in Medicare Parts A and B.[5] Section 120(a)(2)(A) of the CAA established section 1837(m) of the Act to provide the Secretary with authority to establish SEPs for individuals who satisfy the requirements in paragraph (1) or (2) of section 1836(a) of the Act, and meet such exceptional conditions as the Secretary may provide, beginning January 1, 2023. Section 120 of the CAA also created section 1838(g) of the Act to provide the Secretary the discretion to determine the entitlement period for individuals who enroll pursuant to an SEP established according to section 1837(m) of the Act, in a manner that protects the continuity of health benefit coverage to the extent practicable. The CAA also modified section 1839(b) of the Act to exempt individuals who enroll pursuant to an SEP for exceptional conditions established under section 1838(m) of the Act, from paying an LEP. Section 1818(c) of the Act provides that individuals enrolling under premium Part A are generally afforded the same enrollment opportunities as those available under Part B, so our proposals would apply to both premium Part A and Part B, except where noted. Several SEPs currently exist that permit individuals to enroll in premium Part A or Part B outside of the IEP or GEP, including the following:

- Sections 1837(i)(1) through (3) of the Act provide an SEP for certain individuals who are enrolled in a qualified group health plan (GHP) or large GHP (LGHP) at the time they first become eligible for Medicare and elect not to enroll (or to be deemed enrolled) in Medicare during their IEP.
- Section 1837(i)(4) of the Act establishes an SEP for certain individuals who, when first eligible for Medicare, were enrolled in a group health plan (GHP) or large group health plan (LGHP) by reason of their own (or a family member's) current or former employment, and whose coverage ended at a time when enrollment in the plan was not based on current employment.
- Section 1837(k) of the Act establishes an SEP for individuals serving as volunteers outside the United States at the time they first become eligible for Medicare, through a program covering at least a 12-month period, sponsored by a 501(c)(3) tax exempt organization, and who demonstrate health insurance coverage while serving in the program.
- Section 1837(l) of the Act establishes a 12-month SEP for certain individuals who are enrolled in TRICARE and become eligible to enroll in Part A on the basis of disability or ESRD status under sections 226(b) or 226A of the Act, respectively, but who elect not to enroll (or to be deemed enrolled) during their IEP.

There is an appeal process, under SSA guidance, for individuals who are denied for one of the current SEPs. If an individual disagrees with an initial determination or decision, they may request further review under the administrative review process, also known as the appeal process. This process will also apply to the newly established SEPs. We proposed to establish five new exceptional conditions SEPs under section 1837(m) of the Act in §§ 406.27 and 407.23 of the regulations for Medicare parts A and B, respectively. These five SEPs are for individuals impacted by an emergency or disaster, health plans or employers misrepresenting or providing incorrect information, the termination of Medicaid coverage, formally incarcerated, and other exceptional conditions. We proposed that these SEPs would be available to individuals who miss an IEP, GEP, or another SEP, such as the GHP SEP, due to a covered exceptional condition. (We note that in discussing these changes in the preamble of the proposed rule at 87 FR 25092, 25126, and 25128 we erroneously referred to § 407.22 instead of § 407.23 and are now correcting that error.)

In determining what new exceptional conditions SEPs would be beneficial to the Medicare program and its beneficiaries and that should be established in regulations, we

[4] An LEP is an amount added to the monthly premium that can be applied to individuals who do not sign up during their IEP. See 42 CFR 406.32(a) and 408.22.

[5] CMS has separate authority for Medicare Parts C and D under sections 1851(e)(4)(d) and 1860D–1(b)(3)(C) of the Act, respectively.

considered numerous factors including the following:

- Whether the conditions that caused the individual to miss an enrollment period are ''exceptional'' as required under the CAA, and whether the conditions are likely to be a one-time event.
- The SEP should not create an incentive for individuals to delay timely enrollment into Medicare.
- The SEP should not create an incentive for individuals to not educate themselves about the importance of enrolling in Medicare timely and make informed decisions during other available enrollment periods.
- Whether an SEP would be the most appropriate resolution to the exceptional conditions in question and whether other remedies such as individualized equitable relief under section 1837(h) of the Act, would more appropriately apply.
- The SEP should be expected to apply to a significant number or broad category of individuals, which would justify the establishment of a specific SEP in regulation instead of relying on the Secretary's authority under section 1837(h) of the Act to evaluate individual conditions and approve SEPs on a case-by-case basis.

With these parameters in mind, we leveraged our previous program experience with Medicare enrollment in determining which SEPs to propose. We also considered the SEPs for exceptional conditions established under Medicare Parts C and D (section 1851(e)(4) of the Act), the Health Insurance Marketplace (29 U.S.C. 1163), and commercial health plans for insight into what SEPs are available in both public and private healthcare settings. Finally, we also considered whether the proposed new SEPs and the associated entitlement would protect access to continuous coverage for individuals eligible for Medicare Part A and Part B, such as through expediting individuals' entitlement date or by creating opportunities for individuals to enroll in coverage sooner.

Based on these considerations, we proposed to establish five SEPs under Medicare Parts A and B based on the Secretary's authority in section 1837(m) of the Act. Four of the proposed SEPs address specific exceptional conditions. One SEP would permit CMS or SSA to evaluate individuals' particular conditions and grant SEPs on a case-by-case basis due to unanticipated conditions that may arise in the future.

To accommodate these changes, we proposed to establish a new § 406.27, entitled ''Special enrollment periods for exceptional conditions'' to provide SEPs for individuals who missed enrolling in premium Part A during an enrollment period due to exceptional conditions. Similarly, we proposed to establish a new § 407.23, also entitled ''Special enrollment periods for exceptional conditions'' to provide SEPs for individuals who missed enrolling in Part B during an enrollment period due to exceptional conditions. Both proposed §§ 406.27(a) and 407.23(a) provided in part that the SEPs for exceptional conditions would be available beginning January 1, 2023. Specifically, the proposed SEPs for exceptional conditions would be applicable for exceptional conditions that took place on or after January 1, 2023 with the exception of the SEP to Coordinate with Termination of Medicaid Coverage discussed in section II.2.d. of this final rule.

a. Late Enrollment Penalties Associated With Special Enrollment Periods for Exceptional Conditions

Section 120(a)(2)(C)(ii) of the CAA modified section 1839(b) of the Act and provides that individuals who enroll during an SEP established under the Secretary's authority under new section 1837(m) of the Act are not subject to the LEP. Specifically, section 1839(b) of the Act, as amended, provides that an individual who enrolls in Medicare ''after his initial enrollment period [. . .] and not pursuant to a special enrollment period under subsection (i)(4), (l), or (m) of section 1837 [. . .] shall be increased by 10 percent of the monthly premium so determined for each full 12 months (in the same continuous period of eligibility) in which he could have been but was not enrolled.'' Therefore, we proposed the following:

- For enrollments on or after January 1, 2023 under one of the SEPs established pursuant to the Secretary's authority in section 1837(m) of the Act and established in § 406.27 (Special enrollment periods for exceptional conditions), we proposed at § 406.33(c)(2) that any months of non-coverage would be excluded from the calculation of the LEP.
- For enrollments on or after January 1, 2023 under one of the SEPs established pursuant to the Secretary's authority in section 1837(m) of the Act and established in § 407.23 (Special enrollment periods for exceptional conditions), we proposed at § 408.24(b)(2) that any months of non-coverage would be excluded from the calculation of the LEP.
- For individuals who reenroll prior to January 1, 2023, we proposed at §§ 406.34(a) and 408.24(c) that requirements currently in place for determining the months taken into account for purposes of calculating the LEP would continue to apply.
- For reenrollments on or after January 1, 2023, pursuant to one of the SEPs for exceptional conditions established under the Secretary's authority in section 1837(m) of the Act and promulgated in §§ 406.27 or 407.23, respectively, we proposed at §§ 406.34(e) and 408.24(d)(2)(ii) that any months of non-coverage would be excluded from the calculation of the LEP. We clarified in the proposed rule that if the individual fails to enroll or reenroll during the available exceptional condition SEP, any months of non-coverage, including the months during the exceptional condition SEP, would be taken into consideration for calculating the LEP in accordance with §§ 406.33, 406.34, and 408.22.

We received a large number of comments related our proposed SEPs. The discussion pertains to comments related to our overall SEP authority and provides our responses to those comments.

Comment: Commenters supported the five proposed SEPs, including CMS's proposal to exclude months of non-coverage from the calculation of the LEP, and several commenters applauded our efforts to expand access to Medicare coverage with this new rule. Many cited that these new SEPs would add to the agency's commitment to health equity by helping to reduce disparities. A commenter stated that ''these provisions may also help maintain the financial viability of the emergency care safety net.'' Similarly, others agreed with our reasoning for these proposed SEPs, stating that they would address several of the barriers to timely Medicare enrollment and reduce coverage gaps and access to healthcare, including mental health services.

Response: We thank all commenters for their support on the five proposed SEPs. Many of the inferences trumpeted by the commenters align with our reasoning for proposing these provisions. We remain committed to advancing health equity for all by improving access and eliminating barriers, to Medicare.

Comment: A commenter strongly encouraged CMS and SSA to use existing data resources to automatically apply these SEPs for individuals who are able to provide basic documentation with their enrollment materials. They added that CMS and SSA should include information about how the process will be streamlined with notification of the SEP. Furthermore, this commenter urged CMS to consider

alternative communication methods, in addition to mail, to ensure individuals are aware of the SEPs.

Response: We appreciate the suggestion to ease processes for beneficiaries, but we are unable to automatically apply these SEPs for individuals who wish to enroll in Medicare. Use of the proposed SEPs requires that an individual misses their enrollment period due to a qualifying event. For us to know that information, the individual must initiate contact with SSA, which will allow SSA to verify their validity for an exceptional condition SEP. For these reasons, we decline to adopt the commenter's recommendation to automatically apply this SEP to eligible individuals at this time, but we may consider options to work closely with stakeholders to streamline processes in future rulemaking. In regard to alternative methods of communication, we appreciate the suggestion, and CMS is committed to updating our websites and working with stakeholders to ensure adequate awareness of the availability of these new SEPs as appropriate.

Comment: A commenter was concerned that the proposed SEPs were limited to a narrow group of individuals who were specifically enrolled in a group health plan when they first became eligible to enroll in Medicare.

Response: To clarify, the proposed exceptional condition SEPs are available to any individual who qualifies and are not specific to those enrolled in a group health plan when first eligible for Medicare.

b. SEP for Individuals Impacted by an Emergency or Disaster

We proposed an SEP for individuals impacted by a government-declared emergency or disaster under the Secretary's authority to establish SEPs beginning January 1, 2023, under section 1837(m) of the Act. Establishing such an SEP would permit the agency to provide immediate relief to individuals impacted by certain government-declared emergencies and disasters without being subject to the requirements applicable under our existing equitable relief authority.[6] These SEPs would apply for individuals enrolling in premium Part A or Part B and would eliminate potential gaps in coverage and otherwise applicable LEPs resulting from eligible individuals' inability to submit a timely enrollment request as a result of emergency or disaster.

The proposed parameters of this SEP were as follows:

- At new §§ 406.27(b) and 407.23(b), we proposed to create an SEP for individuals prevented from submitting a timely Medicare enrollment request by an emergency or disaster declared by either a Federal, State, or local government.
- At new §§ 406.27(b)(1) and 407.23(b)(1), we proposed that the SEP would be available to those who were not able to enroll in premium Part A or Part B or both if they reside (or resided) in an area for which a Federal, State or local government entity newly declared a disaster or other emergency. The individual must demonstrate that they reside (or resided) in the area during the period covered by that declaration.
- At §§ 406.27(b)(2) and 407.23(b)(2), we proposed that the SEP would begin on the date an emergency or disaster is declared, or if different, the start date identified in the declaration, whichever is earlier, so long as the date is on or after January 1, 2023. The SEP ends 2 months after the declaration has been determined to have ended or revoked. If the declaration is extended, the SEP ends 2 months after the end date of any extensions. We specifically requested comments regarding whether we should limit the time frame of the SEP based on the type of emergency, or specify that the type of emergency must explicitly restrict an individual's ability to enroll.
- We proposed in §§ 406.27(b)(3) and 407.23(b)(3), according to the Secretary's authority under section 1838(g) of the Act to specify the coverage period for individuals enrolling during SEPs established under section 1837(m) of the Act, that the coverage period for individuals who enroll under this SEP would begin the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

We received the following comments on the SEP for Individuals Impacted by an Emergency or Disaster:

Comment: Commenters expressed strong and broad support for the establishment of this SEP. Commenters agree that this SEP would help mitigate disparities related to the access of healthcare for Medicare beneficiaries residing in areas impacted by disasters or emergencies. A few commenters suggested that the proposed duration of the SEP may not be enough time for individuals to recover from a disaster or emergency declaration has ended and one recommended the SEP extend a full year after the declaration has ended.

Response: We appreciate the overwhelming support for this proposed SEP and thank those that gave us feedback. The vast majority of commenters expressed support for the SEP's duration, as proposed. However, we did receive comments suggesting that we extend the duration of the SEP beyond 2 months after the end of the emergency or disaster declaration. Upon review, we have decided to extend the SEP duration in order to provide greater flexibility for potential Medicare beneficiaries. Individuals will have the full duration of the emergency plus an additional 6 months to contact SSA to enroll in Medicare under this SEP. As such, we are revising §§ 406.27(b)(2) and 407.23(b)(2) to specify that the SEP begins on the earlier of the date an emergency or disaster is declared or, if different, the start date identified in such declaration and the SEP ends 6 months after the declaration has been determined to have ended or revoked. If the declaration is extended, the SEP ends 6 months after the end date of any extensions.

Comment: A few commenters requested that CMS consider making the SEP applicable in situations where the individual may not live in an area impacted by a Federal, State or local government-declared disaster or emergency, but the person who makes healthcare decisions on behalf of that individual does, noting that it was consistent to what was allowed in Part C and Part D. Additionally, a commenter recommended that we ensure that moving forward the requirements related to this SEP remain equal across Medicare Parts A, B, C and D.

Response: We thank commenters for this insight. Currently, in regard to the Medicare Part C and D emergency or disaster SEP, if a person who assists in making health care decisions on behalf of a Medicare enrollee is impacted by a government-declared emergency or disaster, then the SEP would be available to the enrollee. We would note that Medicare enrollees in Parts C and D have the option to make enrollment decisions on what plans best suit their financial and health care needs on an annual basis, and they often rely on friends and family members with these decisions. In contrast, enrolling in Parts A and B is normally a one-time decision that does not include the same level of complexity as Parts C and D enrollments. However, we do believe allowing some flexibility to individuals who require assistance in Medicare Parts A and B is important. As such, we will be revising §§ 406.27(b)(1) and 407.23(b)(1) to specify that the SEP is

[6] Equitable relief (section 1837(h) of the Act) is the tool by which we correct or eliminate inequity to the individual when their Medicare enrollment rights are prejudiced because of the error, misrepresentation, or inaction of the federal government.

also available if the individual did not live in an area impacted by a Federal, State or local government-declared disaster or emergency, but the individual's authorized representative (as defined at 42 CFR 405.910), their legal guardian, or the person who makes healthcare decisions on behalf of that individual, did live in such an impacted area.

Comment: A commenter requested that we remove the requirement for the individual to submit proof of SSA office closings or mail disruptions, or provide proof that the emergency or disaster directly affected their ability to enroll in Medicare.

Response: We appreciate the feedback but would like to clarify that impacted beneficiaries are not required to provide proof of SSA office closings or disruptions in mail service due to a disaster or emergency for this SEP. The individual must have missed an enrollment period in order to qualify for this SEP; however, the individual does not have to provide documented proof that the disaster or emergency impacted their ability to enroll as SSA will already have this information. Individuals or their authorized representative need only to demonstrate that they reside (or resided) in the area during the period covered by a disaster or emergency declaration.

Comment: We solicited comments on whether we should limit the SEP timeframe based on the type of emergency or the explicit impact on the individual's ability to enroll. The majority of commenters believe such restriction would be harmful to individuals and administratively burdensome to the Social Security Administration, which is tasked with making enrollment determinations. Commenters believe it is extremely unlikely that anyone would intentionally delay Medicare enrollment in hopes of a tragedy. There also may be disasters or emergencies that do not impact an individual's ability to enroll in Medicare.

Response: We agree with commenters and appreciate their feedback. The purpose of this SEP is to provide an enrollment opportunity for individual's impacted by an exceptional condition that may have impeded their ability to enroll during another valid enrollment period and as such we will not make any changes to the SEP timeframe based on the type of disaster or emergency.

We appreciate the support and feedback received from commenters. As discussed, we will be finalizing this SEP as proposed with the following modifications. We will be revising §§ 406.27(b)(1) and 407.23(b)(1) to specify that the SEP is also available if the individual did not live in an area impacted by a Federal, State or local government-declared disaster or emergency, but the individual's authorized representative (as defined at 42 CFR 405.910), legal guardian (as outlined by SSA), or person who makes healthcare decisions on behalf of the individuals, did live in such an impacted area. In addition, we will be revising §§ 406.27(b)(2) and 407.23(b)(2) to extend the duration of the SEP from 2 months to 6 months after the end of the emergency or disaster declaration.

c. SEP for Health Plan or Employer Misrepresentation or Providing Incorrect Information

In order to provide relief to individuals who missed an enrollment period because of misrepresentation by or incorrect information from their employer or GHP, we proposed to create a new SEP at § 406.27(c) and at § 407.23(c) based on exceptional conditions. We proposed that this SEP would apply for individuals whose non-enrollment in premium Part A or Part B is unintentional, inadvertent, or erroneous and results from material misrepresentation or reliance on incorrect information provided by the individual's employer or GHP, or any person authorized to act on behalf of the employer or GHP.

The proposed parameters of this SEP were as follows:

- At §§ 406.27(c)(1) and 407.23(c)(1) we proposed that an individual is eligible for such an SEP if they can demonstrate that he or she did not enroll in premium Part A or Part B during an enrollment period in which they were eligible based on information received from an employer or GHP, or any person authorized to act on such organization's behalf, and an employer, GHP or their representative materially misrepresented information or provided incorrect information relating to enrollment in premium Part A or Part B, so long as the misrepresentation or error occurred on or after January 1, 2023. We stated that to demonstrate material misrepresentation, an individual would be required to provide documentation of the relevant misrepresentation to SSA and that it must show that the information was provided on or after January 1, 2023, was directly from an employer, GHP or their representative prior to an enrollment period, and that the inaccuracy caused the individual not to enroll timely.
- At § 406.27(c)(2) and § 407.23(c)(2) we proposed that this SEP would begin the day the individual notifies SSA of the employer or GHP misrepresentation or incorrect information provided, so long as the misrepresentation or error occurred on or after January 1, 2023, and would end 2 months later.
- At §§ 406.27(c)(3) and 407.23(c)(3), we propose that the coverage period would begin the first day of the month following enrollment.

We received the following comments on the SEP for Health Plan or Employer Misrepresentation or Providing Incorrect Information:

Comment: Commenters expressed general support for this SEP. Commenters indicated that this SEP will help to cure what they perceive to be one of the most widespread and common enrollment pitfalls facing beneficiaries and will potentially eliminate gaps in coverage. Multiple commenters, while supporting the SEP, recommended that we lower the evidence requirement for the SEP due to erroneous information that may have been provided orally or in another form in which the beneficiary may not be able to provide tangible evidence.

Response: We acknowledge that employers and GHPs do not always communicate information in writing; therefore, it is reasonable to assume that individuals may not have tangible documentation to provide to SSA proving that they were misinformed by their employer or GHP. Not allowing an alternative type of documentation, other than written, would disadvantage beneficiaries who were misinformed through other communication methods. Upon review, we have decided to accept written attestation from the beneficiary when documented evidence from the employer or GHP is not available. We thank the commenters for their overall support, and agree with their assessment of the evidence requirement. We are modifying the regulations at §§ 406.27(c) and 407.23(c) to expressly permit the use of either documentation of misrepresentation or written attestation.

Comment: Many commenters, while supporting the SEP, recommended that we include non-employer insurance sources, such as insurance agents and individual policy sellers, as well as non-federal government entities and agents, including Medicaid, the Marketplace, and State Departments of Insurance or similar as trusted sources of information. Commenters also recommended to expand the definition of misinformation to include employer or health plan omission of information.

Response: Upon review, we agree that other non-employer insurance sources could be considered trusted sources of information. Agents and brokers of health plans could be considered as

extensions of an individual's health plan and play a critical role in informing individuals of their enrollment options. We have modified the language in the regulation text accordingly.

We are not adopting the suggested inclusion of non-federal government entities and agents, including Medicaid, the Marketplace, and State Departments of Insurance as trusted sources of information because this would substantially change the scope of this SEP. The purpose of this SEP is to provide relief to employees who have been misinformed by employers, GHPs, or agents or brokers of health plans. If another entity has misinformed the beneficiary, the individual may apply for relief under the SEP for Other Exceptional Conditions. Accordingly, we are revising §§ 406.27(c)(1)(i) and 407.23(c)(1)(i) to include brokers or agents of health plans as entities from whom the beneficiary may have received misinformation.

Comment: Multiple commenters recommended that CMS expand the definition of misinformation to include employer or health plan omission of relevant information. For example, a commenter stated that an employer or health plan failing to convey pertinent information could impact an individual's decision making and cause them to miss their Medicare enrollment period.

Response: While we understand that individuals need complete information about their options and responsibilities, the onus does not fall on the employer, GHP, or agents and brokers of health plans to provide any information that the individual requests. Information provided by these entities is often voluntary, as they are not legally obligated under the Medicare statute to provide any information to individuals related to Medicare enrollment. As such, we will not be revising this final rule to provide that omission of information can give support an SEP.

Comment: Several commenters discussed beneficiaries' confusion with the interaction of COBRA coverage and Medicare, including that COBRA is not creditable coverage in the same way employer-group coverage is for Medicare and that COBRA cannot pay primary coverage once a person becomes eligible for Medicare. A few commenters recommended that enrollment in COBRA or retiree coverage alone should be used as evidence of misinformation, and therefore an individual in this circumstance should be considered eligible for the SEP.

Response: While we understand that COBRA interaction with Medicare may be confusing, we are unable to make the assumption that enrollment in COBRA was caused by misinformation provided by an employer or group health plan. We cannot assume that the beneficiary did not deliberately choose to enroll in COBRA. As such, we do not consider this an exceptional condition and will not consider enrolling in COBRA alone as a basis for this SEP. If a beneficiary was erroneously instructed by an employer, group health plan, or agent and/or broker of the health plan to enroll in COBRA, they may provide the documented evidence or written attestation of the misinformation in order to qualify for the SEP. In addition, if there was another exceptional circumstance surrounding their enrollment in COBRA, they can apply for the SEP for other exceptional conditions.

Comment: A commenter suggested that we increase the SEP duration from 2 months to 6 months to allow the beneficiary time to gather evidence of the misinformation.

Response: We proposed that the SEP would end 2 months after the individual notified SSA of the misrepresentation and we believed this would be ample time since, in most cases, we assumed that the individual would enroll at the same time they identified the issue to SSA. However, upon review, we have decided to extend the SEP duration from 2 months to 6 months in order to provide greater flexibility for potential Medicare beneficiaries. In addition, we are modifying this SEP to allow for the acceptance of written attestation, which will allow an individual to provide evidence of misinformation even if they do not have or cannot find written evidence from their employer or health plan, it should not take longer than 6 months to satisfy the requirements of this SEP.

We appreciate the support and feedback received from commenters. As discussed, we will be finalizing this SEP as proposed with the following modifications:

- We are modifying §§ 406.27(c)(1) and 407.23(c)(1) to expressly permit the use of either documentation of misrepresentation or written attestation for this SEP.
- We are revising §§ 406.27(c)(1)(i) and 407.23(c)(1)(i) to include brokers or agents of health plans as entities that may have been a source of misinformation.
- We are revising §§ 406.27(c)(2) and 407.23(c)(2) to increase the SEP duration from 2 months to 6 months.

d. SEP for Formerly Incarcerated Individuals

Section 1862(a)(2) and (3) of the Act generally prohibits Medicare payment for otherwise covered services when the individual who is furnished the services is not obligated to pay for them (and no other person has a legal obligation to pay for them) and covered services that are paid for directly or indirectly by a governmental entity (other than under a health program under the Social Security Act). In implementing these provisions, CMS adopted a regulation that prohibits payment for otherwise covered services that are furnished while the recipient is in custody of penal authorities, as such individuals are provided healthcare through their penal institution. As a result, individuals who are enrolled in Medicare but who are in custody of penal authorities as described in 42 CFR 411.4(b) (here, ''incarcerated'' for brevity) are subject to a payment exclusion in Medicare so Medicare does not pay for items and services that might otherwise be paid under Parts A and B. Further, section 202(x)(1)(A) of the Act prohibits the payment of Old-age, Survivors, and Disability Insurance (OASDI) benefits to individuals who meet one of several criteria that relate to being incarcerated.[7] Therefore, if an individual turns 65 and qualifies for Medicare but is not yet receiving OASDI benefits because of section 202(x)(1) of the Act, that individual is not automatically enrolled in Medicare Part A. Further, an individual may elect not to enroll in Medicare while incarcerated to avoid having to pay out of pocket premiums only for Medicare to deny payment for services. Moreover, current law does not provide any special enrollment opportunities for formerly incarcerated individuals who miss a Medicare enrollment period while incarcerated. If these individuals do not enroll into Medicare because they are incarcerated, they may go months without health coverage upon their release.

To address the exceptional conditions that an individual faces upon release from incarceration and to ensure that formerly incarcerated individuals have access to health coverage under Medicare, we proposed. at §§ 406.27(d) and 407.23(d). an SEP for individuals who are released from incarceration on or after January 1, 2023. This SEP would

[7] Section 202(x)(1)(A) lists several conditions of being confined in a jail, prison, other penal institution or correctional facility, or in an institution at public expense for certain reasons specified in the statute, or in a specific status with regard to criminal prosecution. Here, we use the term ''incarceration'' for brevity.

allow those formerly incarcerated individuals to avoid potential gaps in coverage and late enrollment penalties.

The proposed parameters of this SEP were as follows:

- At §§ 406.27(d)(1) and 407.23(d)(1), we proposed that an individual would be eligible for this SEP if they demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Medicare premium Part A or Part B during another enrollment period in which they were eligible to enroll while they were incarcerated. Further, there must be a record of release either through discharge documents or data available to SSA.
- At §§ 406.27(d)(2) and 407.23(d)(2), we proposed that this SEP would start the day of the individual's release from incarceration and end the last day of the 6th month after the month in which the individual is released from incarceration.
- At new §§ 406.27(d)(3) and 407.23(d)(3), we proposed that entitlement would begin the first day of the month after the month of enrollment, so long as it is after January 1, 2023.

We received the following comments on the SEP for Formerly Incarcerated Individuals:

Comment: Commenters including advocacy groups, individuals, and State penal institutions provided broad support for this SEP. These commenters indicated that it could help this population as increasing health services and coverage during reentry have been associated with lower rates of recidivism and improved outcomes around employment, housing, and family support. Multiple commenters, while supporting the SEP, recommended that the duration be extended from 6 months as navigating reentry can be timely and daunting for this population, many of whom may have physical or cognitive impairments and/or low literacy and health literacy. Commenters also cited the heightened risk of competing priorities such as economic and housing insecurity during the period following release from incarceration as the need for an increased SEP duration. Most commenters recommended extending the SEP to 12 months, and a commenter recommended that the SEP last for 2 years.

Response: We appreciate the support for this SEP and understand and agree with the commenters' belief that this population faces many challenges in establishing stable conditions and reintegrating themselves into society. Upon review, and based on the issues raised by the commenters, we are extending the SEP duration to 12 months. We believe encouraging individuals to reestablish healthcare coverage through Medicare is a vital part of successfully re-entering and reintegrating into the community after incarceration and that a 12-month timeframe provides sufficient time for a released individual to have OASDI benefits reinstated. Reinstating OASDI benefits is important, especially to this population, as they can then enroll or reenroll in Medicare and not have to pay out of pocket for Medicare premiums, but rather have their premiums deducted from their Social Security benefits. Not all formerly incarcerated individuals will delay enrollment or reenrollment into Medicare until after they have reinstated their OASDI benefits. However, for those who do, allowing 12 months to enroll or reenroll in Medicare after release from incarceration allows ample time for formerly incarcerated individuals to first have their OASDI benefits reinstated. CMS will conduct education and outreach efforts to inform stakeholders on this SEP and the importance of prioritizing enrollment into Medicare for this population.

Accordingly, we are revising the duration of this SEP at §§ 406.27(d)(2) and 407.23(d)(2) to reflect an SEP that starts the day of release from incarceration and concludes at the end of the 12th subsequent month. For example, if an incarcerated individual was released on January 14, 2023, their SEP would begin on January 14, 2023 and end on January 31, 2024.

Comment: Multiple comments recommended allowing for pre-release enrollment under this SEP in order to prevent against potential gaps in coverage for this population upon release from incarceration. Commenters calling for pre-release enrollment also cited the need for these individuals to receive assistance from the State or incarcerating entity in their enrollment.

Response: We appreciate the feedback from commenters and understand the importance, especially for this vulnerable population, to lessen any risk of gaps of coverage. Further, we understand many individuals of this population may have economic factors that prevent them from enrolling in Medicare prior to their OASDI benefits being reinstated, thus requiring them to pay out of pocket for Medicare premiums. With these considerations in mind, we considered different options to best reduce any gaps of coverage that an individual may face upon release from incarceration and that included either revising the duration of the SEP or revising the entitlement start date. We believe this issue can best be addressed by finalizing our proposal with modifications to allow eligible individuals to choose between 2 effective dates of coverage:

- Option 1: Individuals enrolling in this SEP will have a prospective entitlement to begin the first day of the month following the month of enrollment.
- Option 2: Individuals enrolling in this SEP can opt for a retroactive entitlement date so long as their enrollment is on or after January 1, 2023. If the application is filed within the first 6 months of the SEP, the effective date is retroactive to the date of their release from incarceration. If the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to 6 months after the date of release from incarceration. In addition, beneficiaries who opt for retroactive coverage must pay the premiums for that coverage and we note that installment billing plans are available for beneficiaries who cannot pay the lump sum of retroactive premiums. Beneficiaries would contact their local Social Security field office for help paying any retroactive premium arrearages.

We understand that this population of beneficiaries may face job insecurity and socio-economic barriers while reintegrating into their communities. If an individual opts for retroactive coverage, they would have to pay monthly premiums for those retroactive months of coverage. Some individuals may wish to delay Medicare enrollment until they have had their OASDI benefits reinstated, ensuring they are not paying out of pocket for Medicare premiums. Still others may be willing to pay out of pocket for coverage retroactive to their release date, not to exceed 6 months, and before their OASDI benefits are reinstated. Providing individuals this option allows them the ability to make the healthcare decisions that are best suited to their needs. To implement this change, we are revising the entitlement date of this SEP at §§ 406.27(d)(3) and § 407.23(d)(3) to provide that entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023 or, as we specify in §§ 416.27(d)(3)(ii) and § 407.23(d)(3)(ii), individuals have the option of choosing an entitlement date retroactive to the first day of the month of their release from incarceration, not to exceed 6 months. Individuals would have to pay premiums for the retroactive period of coverage.

Comment: Multiple commenters suggested that CMS revise the

description of when someone is ''in custody of penal authorities'' under § 411.4(b). Commenters identified that the current definition includes a broad range of individuals—including those who are under arrest (pre-conviction), on medical furlough, required to live under home detention, or are on parole, probation, or supervised release. Further, the commenters noted that the regulation at § 411.4 does not absolutely preclude Medicare payment for these individuals; rather, it establishes the presumption that another payer is responsible, and provides that payment may be made for services furnished to individuals or groups of individuals who are in the custody of police or other penal authorities provided that certain conditions are met. However, commenters state the regulation assumes that penal authorities have responsibility to cover, and will cover, medical expenses during all these circumstances, an assumption that is inconsistent with actual coverage by corrections authorities.

Commenters expressed concern that the existing regulation could leave some individuals who are ''in custody of penal authorities'' as that phrase is used in § 411.4(b) without coverage from both the penal institution and Medicare. Commenters described their understanding that Medicaid coverage is permitted for individuals who are ''on parole, probation, or released to the community pending trial; living in a halfway house where individuals can exercise personal freedom; voluntarily living in a public institution; or on home confinement.''

Response: We thank the commenters for their concerns and suggestions. However, changes to § 411.4, such as to limit who is ''in custody'' for purposes of the Medicare payment exclusion or to amend the exception that permits Medicare payment under certain conditions, are not within the scope of this rulemaking. Further, we are not addressing here the rules and definitions used in other programs, such as Medicaid or the Marketplace, for individuals who are incarcerated or in custody.

We believe that it is important that the scope of the SEP we proposed and are finalizing is aligned with who § 411.4(b) specifies are individuals in custody of penal authorities for purposes of the Medicare payment exclusion. However, we appreciate the commenters' considerations and will continue to consider the issues they have raised. As finalized in this rule, §§ 406.27(d) and 407.23(d) use the term ''in custody of penal authorities'' and cite § 411.4(b) for its description of who is in custody of penal authorities to ensure this alignment is clear. As stated in the first paragraph for this section of this final rule, we are using the term ''incarcerated'' in the preamble to describe the individuals who are in custody of penal authorities as described in § 411.4(b). Further, if CMS amends § 411.4(b) in the future to limit the description of who is in custody of penal authorities for purpose of the Medicare payment exclusion, this SEP will be automatically aligned to that change.

Comment: Multiple commenters requested that CMS remove the overdue part B premiums (caused by the 90-day grace period) for incarcerated individuals. Currently, Medicare beneficiaries in a direct-bill agreement (for those who do not have Medicare premiums deducted from their OASDI benefits, a direct-bill agreement is an automatic deduction of Medicare premiums from a checking or savings account each month) are given 90 days to repay any past due premiums before their Medicare enrollment is terminated. After 90 days, Part B enrollment is normally terminated for non-payment of premiums (42 CFR 408.8(c)). Commenters noted this 90-day grace period places an unnecessary and unforeseen financial burden on people who are incarcerated but have not paid prior premiums and creates an additional barrier to reenrollment. The commenters explained this is because most enrolled beneficiaries have Medicare premium payments automatically deducted from a monthly SSA benefit. However, when the enrolled beneficiaries become incarcerated, they are switched to direct payment as their SSA benefits are suspended upon incarceration. If the individual later re-enrolls in Part B after release from incarceration, and upon restoring SSA benefits, SSA deducts premium payments owed under the earlier grace period from the first SSA benefit payment. Commenters noted this deduction can cause significant hardship upon reentry.

Response: We thank commenters for their concerns and suggestions. However, this suggestion is outside the scope of this rulemaking. The Medicare premium grace period is designed to help Medicare beneficiaries who are enrolled in direct pay keep coverage during temporary periods of hardship, or common mishaps that may result in a beneficiary missing a premium payment. Further, incarcerated individuals do have the ability to voluntarily terminate their Medicare coverage upon incarceration to avoid any potential past-due payment issues, which they would do by contacting SSA. Finally, installment billing plans are available through SSA for those who might have trouble repaying back due premiums.

Comment: A commenter requested that CMS use its discretionary authority to revise previous rules and waive all historic LEPs that were paid in the past or are being paid now by previously incarcerated individuals.

Response: By referring to ''historic LEPs,'' we believe the commenter is referring to LEPs that were assessed—and were paid in the past and/or are currently being paid for current Medicare coverage—in connection with coverage periods for individuals who enrolled (or reenrolled) in Part B after ending a period of incarceration before January 1, 2023. This suggestion is outside the scope of this rulemaking, and CMS does not have the authority to unilaterally waive LEPs that were paid in the past or are currently part of an individual's Medicare premium(s) as the LEPs are governed by statute. The Part A LEP is found in the statute at 1818(c)(6) of the Act, and the Part B LEP at 1839(b) of the Act. Section 120(a)(2)(C)(ii) of the CAA modified section 1839(b) of the Act to provide that individuals who enroll during an SEP established under the Secretary's authority under new section 1837(m) of the Act are not subject to the LEP, but it did not provide for a waiver of all historic LEPs for individuals who previously enrolled in Medicare under a condition that now would be considered an exceptional condition or for individuals who may qualify for but do not use an SEP that is established under section 1837(m) of the Act. Therefore, we are unable to waive historic LEPs for individuals who enrolled prior to January 1, 2023, even if that prior enrollment had been under circumstances that will be part of the new SEPs being adopted under section 1837(m) of the Act. Beginning January 1, 2023, an individual who enrolls using one of the SEPs adopted under section 1837(m) of the Act will not be assessed LEPs for the coverage period that begins with that SEP enrollment.

Comment: Multiple commenters recommended that CMS provide education to individuals who may be eligible for this SEP prior to their release from incarceration. Commenters showed concern over this population navigating the Medicare enrollment process and lacking the community resources that non-incarcerated people may have. Further, commenters noted that it would be unlikely that incarcerated individuals would receive any information through the mail about their

IEP, GEP, or any other helpful Medicare literature, therefore causing Medicare enrollment to be a daunting, unfamiliar process. Commenters also recommended that CMS provide notification of this SEP to eligible individuals to ensure that formerly incarcerated individuals can benefit from this SEP.

Response: We thank the commenters for their concerns and suggestions. As a part of implementing this final rule, we will be updating CMS publications, websites, and outreach materials. We also intend to work with stakeholders (for example, SHIPs, beneficiary advocacy groups, etc.) to raise awareness and understanding of all of the new SEPs.

We appreciate the support and feedback received from commenters on this SEP. Based on feedback from commenters, we will be finalizing this SEP as proposed with the following modifications:

- We will be extending the SEP duration and revise §§ 406.27(d)(2) and 407.23(d)(2) to reflect that the SEP starts the day of the individual's release from incarceration and ends the last day of the 12th month after the individual is released from incarceration.
- We are revising the text of the regulations at §§ 406.27(d) and 407.23(d) to use the phrase ''in custody of penal authorities'' as well as citing to § 411.4(b) in order to be clear that the scope of this new SEP is aligned with the scope of § 411.4(b). This change in terminology is intended to eliminate any unintended ambiguity that using different terms in these regulations could produce.
- We are revising the entitlement date of this SEP at §§ 406.27(d)(3) and 407.23(d)(3) to provide that entitlement begins the first day of the month following the month of enrollment. Individuals also have the option of choosing an entitlement date retroactive to the first day of the month of their release from incarceration (not to exceed 6 months).

e. SEP To Coordinate With Termination of Medicaid Coverage

Many beneficiaries are already enrolled in Medicaid when they initially qualify for Medicare at age 65, or if they are under age 65, after receiving 24 months of Social Security Disability Insurance (SSDI). While some of these individuals retain Medicaid coverage after becoming eligible for Medicare, others lose Medicaid benefits and/or eligibility entirely. For example, when an individual enrolled in the adult group under section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR 435.119 becomes eligible for Medicare, they become ineligible for the Medicaid adult group per § 435.119(b)(3).[8]

Unless such individuals are eligible for Medicaid on another basis, such as based on receiving supplemental security income (SSI), they will no longer be eligible for Medicaid. Many such individuals qualify for another Medicaid eligibility group, such as a Medicare Savings Program (MSP) group, but others lose Medicaid coverage entirely because they do not qualify for another Medicaid eligibility group.

Low-income Medicare beneficiaries experience poorer health outcomes than their higher-income counterparts.[9] Based on program experience and reports from stakeholders, we are aware that some individuals who lose all Medicaid coverage after newly qualifying for Medicare may experience confusion and administrative barriers that undermine a seamless transition from Medicaid to Medicare coverage, risking a period of time without health insurance and a possible LEP for these at-risk individuals.

Current Medicaid rules attempt to facilitate beneficiary transitions between Medicaid and other health coverage programs before the beneficiary loses Medicaid coverage. On September 7, 2022, the **Federal Register** included a notice of proposed CMS rulemaking entitled ''*Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes*'' that aims to improve continuity of health coverage; however, for purposes of this rulemaking CMS refers only to current regulations. Before terminating or reducing the scope of Medicaid coverage for individuals who become eligible for Medicare, the State Medicaid agency must conduct a redetermination of eligibility, including a determination of whether the individual is eligible for Medicaid on another basis under §§ 435.916(d), 435.916(f)(1) and 435.930(b). The State must continue the same level of Medicaid coverage until the State completes the eligibility redetermination and provides at least 10 days of advance notice and fair hearing rights in accordance with § 435.917 and 42 CFR part 431 subpart E. If, during the redetermination process, an individual is found to no longer be eligible for the eligibility group under which they had been most recently receiving coverage, the State must then: (1) move the individual to a different eligibility group for which the individual is eligible or, (2) in instances in which the individual is not eligible for another Medicaid eligibility group, determine the individual's potential eligibility for other insurance affordability programs, in accordance with § 435.916(f)(2), and terminate the individual's Medicaid coverage.

In the proposed rule (87 FR 25098), we noted that, despite these requirements, there are multiple scenarios that can prevent a seamless transition to Medicare coverage. We explained that States sometimes fail to complete redeterminations timely, sometimes not until months after the individual first qualifies for Medicare.[10] When this happens, an individual may retain Medicaid even though the individual no longer technically meets the Medicaid eligibility criteria. State Health Insurance Assistance Programs (SHIPs) and beneficiary advocacy groups have reported that such individuals sometimes miss their IEP because they continue to be covered by Medicaid and assume it is not necessary for them to sign up for potentially duplicative health coverage. Moreover, many States do not cover the Part B premiums for individuals remaining in the adult group pending a redetermination under their buy-in agreement.[11] Because individuals in

[8] To date, 39 States have chosen to cover the adult group under § 435.119 (b). The adult group has an income limit of 133 percent of the FPL, but a basic standard deduction of 5 percent of the FPL is applicable as described in section 6012(a)(1) of the Internal Revenue Service Code. (See 42 CFR 434.603(e).

[9] For information about the health outcomes of low-income Medicare beneficiaries, see HHS Office of the Assistant Secretary for Planning and Evaluation (2016, December). *Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//171041/ASPESESRTCfull.pdf.*

[10] Recent HHS Office of Inspector General reports and State audits have cited cases in which States continued to provide coverage for many months after a change impacting eligibility was identified that should have prompted a redetermination. See for example: Louisiana Legislative Auditor. (2018, November 8). *Medicaid Eligibility: Wage Verification Process of the Expansion Population. https://www.lla.la.gov/PublicReports.nsf/1CDD30D9C828608286258340065E5F6/$FILE/0001ABC3.pdf; Colorado Did Not Correctly Determine Medicaid Eligibility for Some Newly Enrolled Beneficiaries. https://oig.hhs.gov/oas/reports/region7/71604228.pdf;* HHS Office of the Inspector General. (2019b, August). *California Made Medicaid Payments on Behalf of Newly Eligible Beneficiaries Who Did Not Meet Federal and State Requirements. https://oig.hhs.gov/oas/reports/region9/91602023.pdf;* HHS Office of the Inspector General. (2018, February). *New York Did Not Correctly Determine Medicaid Eligibility for Some Non-Newly Eligible Beneficiaries. https://oig.hhs.gov/oas/reports/region2/21601005.pdf;* HHS Office of the Inspector General. (2019, July).

[11] Under their buy-in agreements with CMS, some States are required to enroll all Medicaid

Continued

such States would need to pay the Part B premium themselves, they may decline to sign up for Medicare coverage, which they may struggle to afford.

During the ongoing Public Health Emergency in response to the Coronavirus Disease 2019 outbreak (COVID–19 PHE), as a condition of receiving the federal medical assistance percentage (FMAP) increase authorized by the Families First Coronavirus Response Act (FFCRA) (Pub. L. 116–127), States claiming the FMAP increase have been required to maintain Medicaid enrollment for nearly all individuals enrolled in Medicaid as of March 18, 2020, through the end of the month in which the COVID–19 PHE ends. This condition, known as the continuous enrollment requirement or continuous enrollment condition, applies to, among others, individuals who qualified for or were enrolled in Medicaid during this time period in the adult group and subsequently became eligible for Medicare.

As discussed in the proposed rule (87 FR 25099), since the start of the COVID–19 PHE, beneficiary advocacy groups and SHIPs have reported to us that a substantial number of beneficiaries who became eligible for Medicare while enrolled in the Medicaid adult group may have interpreted States' notifications that their Medicaid coverage would remain intact throughout the COVID–19 PHE (and the ensuing months of continuous coverage after they qualified for Medicare) to mean they did not need to take any action during the COVID–19 PHE to secure or maintain health coverage, including enrolling in Medicare. Consequently, we anticipated that some beneficiaries who maintained adult group eligibility are likely to have missed their IEPs as a result of confusion based on the COVID–19 PHE. Based on these reports, we indicated concern that when the COVID–19 PHE ends and states resume routine eligibility and enrollment operations for Medicaid, including taking action on pending redeterminations necessitated by changes in beneficiary circumstances, such individuals would end up being terminated from Medicaid and would experience a gap in coverage and lose access to critical health care as a result. Further, we explained that once they do enroll in Medicare, they could incur late enrollment penalties.

As mentioned previously, under an existing requirement under the Medicaid program designed to maximize continuity of coverage for beneficiaries whom States have determined ineligible for Medicaid, States must determine or assess their potential eligibility for other insurance affordability programs, such as the Children's Health Insurance Program (CHIP) and health insurance coverage available on the Marketplace with financial assistance and transfer their accounts to such programs as appropriate under §§ 435.916(f)(2) and 435.1200(e). As discussed in the proposed rule (87 FR 25099), although insurance affordability programs have not been defined to include Medicare, promoting a seamless transition from Medicaid to Medicare coverage is also very important. The ability to enroll in Medicare can be vital in preventing gaps in health coverage, especially if individuals lack access to other health insurance and may be subject to an LEP when they do enroll in Medicare.

To remove barriers that present an exceptional condition that could prevent individuals from transitioning from coverage under the Medicaid program to coverage under the Medicare program, we proposed an SEP at §§ 406.27(e) and 407.23(e) for individuals who lose Medicaid eligibility entirely after the COVID–19 PHE ends or on or after January 1, 2023 (whichever is earlier) and have missed a Medicare enrollment period. We anticipated our proposals would advance health equity by improving low-income individuals' access to continuous, affordable health coverage and use of needed health care consistent with the *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* and the *Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage.*

We proposed at §§ 406.27(e)(1) and 407.23(e)(1) that to be eligible for this SEP, an individual must demonstrate they are eligible for Medicare and their Medicaid eligibility is terminated on or after January 1, 2023, or is terminated after the last day of the COVID–19 PHE as determined by the Secretary, whichever is earlier. At §§ 406.27(e)(2)(i) and 407.23(e)(2)(i), we proposed that if the termination of Medicaid eligibility occurs after the last day of the COVID–19 PHE and before January 1, 2023, the SEP starts on January 1, 2023 and ends on June 30, 2023. At §§ 406.27(e)(2)(ii) and 407.23(e)(2)(ii), we proposed that if the termination of Medicaid eligibility occurs on or after January 1, 2023, the SEP starts when the beneficiary receives notice of an upcoming termination of Medicaid eligibility and ends 6 months after the termination of eligibility. We anticipated that this extended duration would allow this at-risk population sufficient opportunity to enroll in Medicare.

We also noted that, unlike the other proposed SEPs for exceptional conditions, this SEP could apply to a circumstance that occurs before January 1, 2023 (that is, if the end of the COVID–19 PHE and the individual's Medicaid termination occur before such time). We maintained that such a deviation was warranted in this limited circumstance given the novel COVID–19 outbreak and unprecedented Federal, State, and local efforts to combat it.

We proposed at §§ 406.27(e)(3) and 407.23(e)(3) that entitlement to Part A and Part B, respectively, would begin the first day of the month following the month of enrollment, so long as it is effective after the end of the COVID–19 PHE or January 1, 2023, whichever is earlier. We noted that individuals whose Medicaid eligibility is terminated after the end of the COVD–19 PHE, but before January 1, 2023 (if applicable), have the option of requesting that entitlement begin back to the first of the month following termination of Medicaid eligibility provided the individual pays the monthly premiums for the period of coverage.

Lastly, we proposed at §§ 406.27(e)(4) and 407.23(e)(4) that individuals who otherwise would be eligible for this SEP, but enrolled in Medicare during the COVID–19 PHE prior to January 1, 2023, if applicable, are eligible to have LEPs collected under §§ 406.32(d) or 408.22 reimbursed and ongoing penalties removed. Given the unique nature of this specific SEP, and the fact that we proposed that individuals could be eligible for the SEP if the COVID–19 PHE ends before January 1, 2023, we concluded that it is appropriate and fair that these individuals not be subject to an LEP that would not have been collected had they known about this remedy at the time of enrollment.

We received the following comments, and our responses follow.

Comment: Several commenters expressed general support for the SEP to Coordinate with Termination of Medicaid Coverage (Medicaid SEP) as

beneficiaries in Medicare Part B and to pay the premiums on their behalf (known as ''Part B buy-in''). If such a State has not completed the eligibility redetermination for an individual enrolled in the adult group before the first month they qualify for Medicare, the State must enroll the individual in Part B buy-in for all months in which the individual is enrolled in the adult group. CMS Manual for the State Payment of Medicare Premiums, chapter 1, section 1.4, *https://www.cms.gov/files/document/chapter-1-program-overview-and-policy.pdf.* See section II.D.3.e. of this proposed rule for a discussion of buy-in coverage groups available for Part B.

proposed. Some commenters were particularly appreciative of the reimbursement of the LEPs for individuals who would have been eligible for the Medicaid SEP, but already enrolled in Medicare.

Response: We appreciate the comments in support of our proposal. We anticipate this proposal will help support continuous coverage for individuals as they transition from Medicaid to Medicare coverage after the COVID–19 PHE ends and beyond.

Comment: A few comments sought to further address potential gaps in coverage during the transition from Medicaid to Medicare coverage. A commenter recommended that we require States to continue Medicaid enrollment until the individual is actually enrolled in Medicare.

Response: We lack the statutory authority to require that Medicaid enrollment continue for individuals who are ineligible for Medicaid beyond the end of the COVID–19 PHE and until the individual is actually enrolled in Medicare. Beginning the month following the month in which the COVID–19 PHE has ended, individuals who are ineligible for Medicaid may not remain enrolled in Medicaid after the State makes a redetermination that they are ineligible for such coverage.[12] Therefore, we are unable to accept the commenter's recommendation.

However, we share the commenters' concerns about gaps in health coverage as individuals transition from Medicaid to Medicare health coverage. Under the proposal, the effective date of the Medicare enrollment is the month following the month of the SEP enrollment. Therefore, if individuals do not apply for this SEP upon receipt of the Medicaid termination notice, they would likely have a gap in coverage before Medicare coverage starts. Any delay in applying for this SEP after the loss of Medicaid coverage could be particularly harmful for people who may need to seek medical care in the intervening time. As such, to address the commenters' concerns and reduce gaps in coverage for individuals transitioning between Medicaid and Medicare coverage, we are finalizing revisions to § 406.27(e)(3) to add paragraph (iii) and § 407.27(e)(3) to add paragraph (iii) to allow individuals the option to elect retroactive Medicare entitlement back to the date of Medicaid termination but no earlier than January 1, 2023. If an individual selects this option, they must pay the premiums for the retroactive covered time period.

Comment: A few commenters requested clarification on whether individuals who are only entitled to Part A if they pay a premium (premium Part A) and live in group payer States can use this SEP to enroll in premium Part A for the purposes of enrolling in the Qualified Medicare Beneficiary (QMB) eligibility group.

Response: Under proposed § 406.27(e), individuals who are entitled to premium Part A, have missed their initial Medicare enrollment, and lose all Medicaid eligibility have access to this SEP. We do not make a distinction between access to this SEP for individuals who live in States that have elected to extend their buy-in agreement to include Medicare Part A (Part A buy-in States) and those that did not (group payer States).[13] As such, individuals who are entitled to Part A and live in a group payer State may also use this SEP to enroll in premium Part A under existing SSA processes.

Comment: A few commenters expressed concern regarding the type of notice that would be required before an individual is able to use the SEP. The commenters expressed concern that individuals may not receive timely Medicaid termination notices because of recent relocations, homelessness, and/or mail delivery problems. The commenters suggested these problems may be magnified by the end of the COVID–19 PHE. As such, commenters suggested that CMS use actual knowledge of the Medicaid termination as the standard for when the Medicaid SEP time period should start. A commenter requested that CMS and SSA use existing data resources to automatically apply these SEPs for individuals who are able to provide basic documentation with their enrollment materials.

Response: We share commenters' concerns about timely receipt of a State Medicaid termination notice and reducing barriers to qualifying for this SEP, but we decline to change the notice standard for the SEP to actual notice of termination. We think such a change would be problematic to operationalize because it would be very difficult to verify when any particular individual had actual knowledge of termination of their Medicaid coverage. This modification could also result in delaying the SEP until many months after the individual lost Medicaid coverage, which would undermine the goal of smooth transitions of coverage between the Medicaid and Medicare programs. However, if the individual lacks the original State termination notice, SSA will use alternative processes to verify the loss of Medicaid with the State Medicaid agency (for example, email and telephone contact).

In addition, to prepare for the unwinding of the COVID–19 PHE, we have urged individuals to update their contact information with States at *https://www.medicaid.gov/resources-for-states/coronavirus-disease-2019-covid-19/unwinding-and-returning-regular-operations-after-covid-19/renew-your-medicaid-or-chip-coverage/index.html.* We have also created a list of best practices for State Medicaid agencies as they prepare to unwind the COVID–19 PHE, which includes strategies to collect and verify updated enrollee contact information at *https://www.medicaid.gov/resources-for-states/downloads/state-unwinding-best-practices.pdf.* These principles and practices have been emphasized throughout CMS materials related to unwinding, which can be found at *https://www.medicaid.gov/unwinding.* We encourage the commenters to partner with us to help ensure State Medicaid agencies have updated contact information for beneficiaries.

We appreciate the suggestion to ease processes for beneficiaries but we are unable to automatically apply the Medicaid SEP for individuals who try to enroll in Medicare at the end of the COVID–19 PHE. While some individuals in Medicaid who are eligible for Medicare will lose eligibility for Medicaid upon the end of the COVID–19 PHE, others will not. Some individuals will transition to an MSP eligibility group or another eligibility group that is part of the State's buy-in group. Therefore, we decline to adopt the commenter's recommendation to automatically apply this SEP to eligible individuals at this time, but may consider options to streamline processes in future rulemaking based on program experience.

Comment: Some commenters stated that our proposal to require Medicaid termination as the trigger for the SEP would complicate processes for individuals who missed their IEP during the PHE but who remain eligible for Medicaid after the PHE ends and redeterminations resume. The commenters stated, for example, that in a State that requires Medicare application as a condition of Medicaid eligibility, individuals who are otherwise eligible for Medicaid but failed to enroll in Medicare timely would only be able to qualify for the

[12] The continuous enrollment provision in the FFCRA provides an exception to this rule, but it is limited to the COVID–19 PHE.

[13] For more information about the distinction between a Part A buy-in State and group payer State, please refer to section II.D.1. of this final rule.

SEP if the State terminates their Medicaid eligibility for failing to enroll in Medicare. However, once the individual enrolls in Medicare using the SEP, they would then need to re-apply for Medicaid to regain Medicaid coverage. The commenters therefore requested that CMS consider allowing individuals who missed their IEP to qualify for the SEP without being terminated from Medicaid.

Response: We share the commenters' goal of avoiding administrative complications for individuals and States, but we decline to extend this SEP to individuals who missed their IEP but have not had their Medicaid coverage terminated. At the outset, as noted at 87 FR 25100, individuals who continue to qualify for a Medicaid eligibility group that is included in the State buy-in agreement would not need to use this SEP, as the State would already enroll them in Medicare without regard to Medicare enrollment periods and LEPs.

However, individuals who missed their IEP and remain eligible for a Medicaid group that is *not* in the buy-in agreement could not enroll in Medicare outside of enrollment periods using the proposed SEP. While this group could benefit from the commenters' suggestion, we would need to further explore the policy and operational considerations of broadening the eligibility for this SEP (for example, how to effectively identify the specific affected population) and would benefit from additional public input and program experience. Lastly, we note that individuals who are ineligible for this SEP may still qualify for an SEP on a case-by-case basis for other unanticipated situations that involve exceptional conditions that occur on or after January 1, 2023 at new §§ 406.27(f) and 407.27(f).

Finally, we would like to clarify CMS policy on requiring Medicare as a condition of Medicaid eligibility. As described in the buy-in provisions in the proposed rule at 87 FR 25120, States can require Medicaid applicants and beneficiaries to apply for Medicare as a condition of eligibility, only provided that the State pays their Medicare premiums under the State buy-in agreement. If the State does not pay the Medicare premiums for a Medicaid beneficiary under State buy-in and they do not enroll in Medicare, the State cannot terminate the individual for failing to apply for Medicare.

Comment: Another commenter sought clarification on how the SEP would apply to individuals who failed to timely enroll in Medicare because they remained enrolled in adult group coverage during the PHE and are then enrolled in Medicaid with a spenddown amount after normal operations resume. These individuals have countable income over the eligibility limit for Medicaid and must deduct their incurred medical expenses to reduce their income down to the medically needy income level (''spenddown amount'') in order to be eligible for Medicaid in a given period. The commenter inquired whether individuals with a spenddown amount are eligible for this SEP, particularly if they do not meet their spenddown amount during a given period either because their medical expenses have dipped or they did not submit the necessary paperwork to prove they have met their spenddown amount.

Response: We acknowledge the difficulties and variability of Medicaid eligibility for individuals who must meet a spenddown to qualify for Medicaid. We clarify that the proposed SEP would not apply to individuals who apply for Medicare when they have already met their spenddown amount because they are still eligible for Medicaid. On the other hand, the SEP would apply to individuals if they fail to meet their spenddown amount in a given period and apply using the SEP while their Medicaid coverage is not in effect. We will welcome feedback on experiences with this SEP among individuals who must meet a spenddown to qualify for Medicaid to inform future rulemaking.

Comment: A commenter sought clarification on whether certain individuals would qualify for the proposed SEP. In particular, the commenter questioned whether the SEP applies to individuals who missed a Medicare enrollment period before the COVID–19 PHE began. The commenter also inquired whether individuals can qualify for the SEP if they voluntarily withdraw from Medicaid before the end of the COVID–19 PHE. Finally, the commenter requested we explain if States or an individual can request exceptions to the parameters of the proposed SEP.

Response: We appreciate the commenter's questions. Under §§ 406.27(e)(1)(ii) and 407.27(e)(i)(ii), the SEP is available to individuals who have missed a Medicare enrollment period and whose Medicaid eligibility is terminated on or after January 1, 2023 or is terminated after the last day of the COVID–19 PHE, whichever is earlier. We did not specify when an individual must have missed a Medicare enrollment period. Therefore, in the commenter's first example, an individual who missed a Medicare enrollment period prior to start of the COVID–19 PHE (for example, January 31, 2020) and meets other applicable requirements under §§ 406.27(e) and 407.27(e) would qualify for the SEP.

In response to the commenter's question about voluntary withdrawals, we note at the outset that voluntary terminations from Medicaid are exceedingly rare and, as such, we do not expect the issue the commenter raised to occur with any frequency. Nonetheless, we clarify that this SEP would not apply to individuals who were determined ineligible for Medicaid but kept enrolled due to the continuous coverage enrollment provision in the FFCRA and who voluntarily withdraw from Medicaid before the PHE ended (or individuals who give up Medicaid coverage on or after January 1, 2023). The rationale for this SEP was predicated on ensuring smooth transitions between the Medicaid and Medicare programs, trying to remedy the gaps in coverage that are created through involuntary delayed terminations of Medicaid and the challenges of navigating different States' processes with regard to redeterminations. It is our understanding that individuals who voluntarily terminate their Medicaid coverage would not experience the same gaps in health coverage that individuals facing involuntary terminations experience. Based on program experience, individuals who give up Medicaid coverage tend to have other available sources of health coverage. Additionally, individuals who voluntarily terminate Medicaid coverage do not have the same challenges with States' processes that individuals who are involuntarily terminated from Medicaid experience.

Finally, we did not propose an option for individuals or States to request an exception to the parameters of this proposed SEP. However, as noted previously, individuals who are ineligible for this SEP may still qualify for an SEP on a case-by-case basis for other unanticipated situations that involve exceptional conditions that occur on or after January 1, 2023 at new §§ 406.27(f) and 407.27(f). After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposal with a modification to our proposed SEP at §§ 406.27(e) and 407.27(e) to allow retroactive entitlement to the date of termination of Medicaid coverage but no earlier than January 1, 2023.

f. SEP for Other Exceptional Conditions

We also proposed to retain the ability to provide SEPs on a case-by-case basis for other unanticipated situations that involve exceptional conditions and warrant an SEP. This SEP would allow us to grant SEPs on a case-by-case basis for circumstances we do not have enough experience to consider or anticipate that could create a barrier to enrollment. We acknowledge that there is no way to predict the full range of circumstances that would warrant an SEP—they are ''exceptional''—so we need this SEP for exceptional conditions to be timely in our response to beneficiaries with unique cases, given the time it takes to establish a more targeted SEP via rulemaking.

The proposed parameters of this SEP were as follows:

- At §§ 406.27(f) and 407.23(f), we proposed to create an SEP that would provide an enrollment opportunity for individuals where conditions beyond their control caused them to miss an enrollment period and prevented them from timely enrolling in premium Part A or Part B or both during the IEP, GEP or other prescribed SEPs.
- At §§ 406.27(f)(1) and 407.23(f)(1), we proposed that such SEPs would be granted on or after January 1, 2023, if the individual demonstrates that conditions outside of their control caused them to miss an enrollment period and the condition was determined exceptional in nature.
- At §§ 406.27(f)(2) and 407.23(f)(2), we proposed that the SEP duration would be determined on a case-by-case basis
- At §§ 406.27(f)(3) and 407.23(f)(3), we proposed that entitlement would begin the first day of the month following the month of enrollment, and only for exceptional conditions that arise on or after January 1, 2023.

We received the following comments on the SEP for Other Exceptional Conditions:

Comment: Commenters expressed incredible support for the case-by-case SEP, and many commenters included suggestions to establish new, separate SEPs along with those discussed in the proposed regulation. For example, some commenters urged us to expand this SEP to include certain socio-demographic groups. Notably, a few commenters expressed support and suggested a separate SEP for immigrants who have passed the 5-year requirement, but are under the impression that they need to wait until citizenship before they can enroll in Medicare. This misinterpretation inadvertently causes them to miss their IEP. The commenter detailed that the underlying issue is a misunderstanding of eligibility for Medicare for immigrants and a lack of notice, hence the need for a new SEP instead of individual equitable relief.

Similarly, another commenter urged CMS to grant a new SEP, or waive the LEP, to eligible American Indian and Alaska Native individuals if they inadvertently miss their IEP due to the complicated nature of the Indian health care delivery system. They cited that such an opportunity would fall in line with the agency's commitment to improving the health of this population and eliminate barriers to enrollment and coverage.

Response: We acknowledge and appreciate all comments received. Under §§ 406.20(b)(2)(ii) and §§ 407.10(a)(2)(iii), immigrants over age 65 can qualify for, and enroll in, premium Medicare Part A and Part B after 5 continuous years of legal residency in the United States. Individuals who identify as American Indian and Alaska Native are able to seek and receive care through the Indian Health Service (IHS). Because the IHS works closely, and often in tandem with CMS, Medicare coverage information is readily provided to entitled beneficiaries who interact with the system.

With this understanding, we believe there are avenues through which individuals within these populations can receive adequate and accurate information about Medicare eligibility and enrollment. While we are sensitive to the conditions presented, we do not see a need to revise our regulations or establish a new, separate specific SEP for these groups as it is not clear to CMS that they meet the definition as exceptional conditions and we do not have evidence that the potential exceptional conditions impact a broad enough group of individuals to necessitate the establishment of a specific SEP. An individual who can present documentation to SSA that an exceptional condition that was outside their control prevented that individual from enrolling in Medicare may qualify for the Other Exceptional Conditions SEP on a case-by-case basis. CMS will work with SSA to monitor the use of the Other Exceptional Conditions SEP, and if a particular exceptional condition that impacts a broad number of individuals becomes apparent in that data analysis, we will consider adding additional specific SEPs in the future.

Ultimately, we remain committed to improving education and outreach efforts for these populations to remedy current misunderstandings, bridge knowledge gaps, and eliminate enrollment barriers. We will continue to partner with existing stakeholders to ensure that clear and comprehensive information is provided to beneficiaries so they are able to make an informed coverage choice in a timely manner. We will also continue to evaluate the data collected on the case-by-case exceptional conditions SEP to determine whether any issues arise that warrant the creation of a unique exceptional conditions SEP for these populations.

Comment: A few commenters mentioned the existing SEP for individuals serving as volunteers outside the U.S. at the time they first become eligible for Medicare who are participating in a program sponsored by a 501(c)(3) covering at least a year, and who demonstrate health insurance coverage while serving in the program. Consequently, they urged CMS to expand the existing SEP for those living abroad who have been covered by private or national insurance, in that country and wish to return to the U.S. and enroll in Medicare.

Response: We acknowledge and thank the commenters for their input. Under SSA publication No. EN–05–10137,[14] for an individual living abroad who may be eligible for Medicare, there are generally no restrictions from collecting Social Security benefits and enrolling in Medicare. This applies regardless of if they return to reside in the United States or not. Additionally, individuals who live abroad are able to still pay their premium, if required, and be enrolled in Medicare Part A or Part B during their IEP. Given that there are not any exceptional conditions that prevent these individuals from enrolling in Medicare, we do not believe that an expansion on the current SEP, or creation of a new, separate SEP is warranted under this circumstance. (We note that Medicare generally does not pay for services that are not furnished within the United States. See 42 CFR 411.9.)

Comment: Another commenter urged CMS to consider establishing an additional SEP for individuals who have relied on coverage from the Veterans Administration (VA). Specifically, they cited that after these individuals missed their IEP for Medicare and realized that the VA coverage no longer meets all of their needs, they want a new opportunity to enroll in Part B.

Response: Veterans, like all other Medicare beneficiaries, who receive Social Security benefits at the time they reach age 65 receive a notice about

[14] *https://www.ssa.gov/pubs/EN-05-10137.pdf.*

Medicare coverage, regardless of VA coverage. In addition, for those not collecting Social Security benefits at age 65, there are a number of resources available to those receiving VA health benefits that advise them to enroll in Medicare on their own, or if applicable, their spouse's record as described on pages 19 and 90 of the 2022 *Medicare and You Handbook* for additional information. The guidance also explains the resulting consequence for not filing, especially in situations where he or she is not eligible for premium-free Part A based on their own work record.

For these reasons, we do not concur with the need for a specific SEP for this population. We will continue to refine awareness and education efforts on eligibility and enrollment for this target population to help to eliminate barriers to timely enrollment.

Comment: Another commenter suggested that CMS create a permanent, separate SEP for individuals who were given erroneous information by an SSA or other federal employee. They note that, while equitable relief is typically available for such situations, SSA is not required to reply to these requests within a specific timeframe, therefore, causing beneficiaries to wait for months or initiate contact for a reply. The commenter also noted that there is no formal appeal process for a denied request.

Response: We thank the commenter for this insight, however, the SEP is not intended to replace equitable relief available under section 1837(h) of the Social Security Act and codified at 42 CFR 407.32. There are specific parameters for the exceptional conditions SEP, as outlined in the proposed rule, including that the reason for the SEP must be exceptional in nature, should not create incentive to delay enrollment in Medicare, and is the most appropriate resolution. The equitable relief process offers additional flexibility that goes beyond the parameters of the exceptional conditions SEP. By providing equitable relief, SSA has the ability to offer additional relief to enrollees such as retroactive coverage, waived premiums, or creation of an enrollment opportunity to essentially eliminate the effects of the government error and meet their coverage needs. Although SSA is not required to process equitable relief requests in a specific timeframe, they aim to process these requests within 30 days from the time it is assigned to a technician. Once the case is processed, the technician notifies the enrollee, in writing, to explain the type of relief granted or if the request for relief is denied. This timeline may be altered due to the need for SSA to solicit additional documentation or verify submitted documentation.

Finally, in response to the commenter's concern about the appeals process for equitable relief. We will continue to collaborate closely with SSA to be as transparent as possible with the equitable relief process, and that options to enroll in Medicare remain accessible.

Comment: A commenter recommended that CMS should consider implementing an SEP for individuals who lose Medicare coverage for failure to pay premiums such that it can only be used twice per beneficiary. They cited that this kind of SEP would avoid the cyclical re-enrollment process for individuals who are unable to pay their premiums.

Response: As discussed in the proposed rule, the scope of the exceptional conditions SEP is intended to provide a new enrollment opportunity and remove any penalties for late enrollment, not to provide premium relief. CMS does not consider non-payment of premiums for economic reasons as a primary justification for an exceptional condition, therefore, this would not fall under the new SEP umbrella. Non-payment of premiums could qualify though as a secondary outcome of a major event that could qualify as an exceptional condition. Further, when individuals do not enroll in Medicare in a timely manner, it puts them at risk for experiencing gaps in coverage and delays in needed health care treatment. Also, as stated in the proposed rule, if an individual is experiencing financial constraints, there are mechanisms in place (including State buy-in, MSP and premium payment plans) that would more appropriately provide support for affected individuals while ensuring continuity in their health care coverage. For these reasons, we will not be establishing a new, separate SEP for this condition.

Comment: A commenter recommended that SEPs be established in Medicare Parts C and D to coordinate with the enrollment period and effective date changes in this rule. They added that we also consider creating a new SEP for MA-only plans for those who enroll in Part B (and premium Part A) during the GEP.

Response: We appreciate the thought supporting this comment. The establishment of new SEPs for Medicare Parts C and D is outside the scope of this rule making.

Comment: Several commenters applauded our desire to use the information and experience gained from the flexibility of this newly established SEP to inform the creation of future SEPs. In their support, they also suggested that we and, to the extent relevant, the SSA track and report any trends or patterns in the use (and limitations) of these new SEPs.

Response: We appreciate the support and recommendation. We expect that the flexibility of this SEP will inform any changes that may be desirable in the future. In order to provide for additional flexibility, and reduce confusion, we are revising the duration of the SEP to establish a minimum time period. Specifically, we are revising §§ 406.27(f)(2) and 407.23(f)(2) to state that the SEP duration is determined on a case by case basis, but will be no less than 6 months.

We do plan to track trends and utilize the data from any frequently occurring situations to help guide discussions regarding the creation of new SEPs, which would be subject to further notice and comment rulemaking. In regards to publicly reporting these trends, we will consider in the future whether sharing data is appropriate and feasible given potential beneficiary privacy concerns.

Comment: A commenter from a health plan supported our proposals, but had some questions with regard to the logistical technicalities. Specifically, they wanted to know how we will designate the SEP reason codes and if they will be released as part of new CY 2023 guidance. Another commenter also questioned if we will be making the determinations around the exceptional conditions and how the process will work overall.

Response: We thank the commenters for their recommendations to clarify several factors of this new SEP. For Part C/D SEPs, health plans are required to submit reason codes to CMS, however, as the SEPs in this regulation are Medicare Part A/B SEPs, they will be submitted to, and determined by, SSA and SSA will code which SEP is used for enrollment. Health plans would have no role in this determination process. We will continue to work alongside SSA to clarify guidelines regarding the exceptional conditions.

We acknowledge and appreciate all of the feedback and supportive comments we received on the proposed SEP for other exceptional conditions. As discussed above, we will be finalizing this SEP with modifications at §§ 406.27(f)(2) and 407.23(f)(2) to state that the SEP duration is determined on a case-by-case-basis, but will be no less than 6 months.

3. Technical Correction to the Calculation of the Late Enrollment Penalty for Individuals Enrolling on or After January 1, 2023

Currently, section 1839(b) of the Act specifies that the LEP is based on the number of months that have elapsed between the close of the individual's IEP and the close of the enrollment period during which they enroll, plus certain additional months for individuals who reenroll. However, section 120(a)(3) of the CAA amended section 1839(b) of the Act to specify that, for enrollments on or after January 1, 2023, the months that will be taken into account for purposes of determining any LEP include months which elapse between the close of the individual's IEP and the close of the month in which they enroll, plus, for individuals who reenroll, the months that elapse between the date of termination of previous coverage and the close of the month in which the individual enrolls. We expect that these changes will decrease the number of months individuals are subject to the LEP. To implement these changes, we proposed the following changes to our regulations:

- At § 406.33, we proposed to revise paragraph (a) to reflect the requirement that, for individuals enrolling for the first time, the existing Part A LEP calculation requirements continue to apply to enrollments before January 1, 2023.
- At § 406.33, we specified that the months to be counted for calculating the Part A LEP begin with the end of the individual's IEP, and extend through the end of the month in which the individual enrolls.
- At § 406.33(c)(1), we proposed to continue to exclude certain months from the calculation of the LEP, based on the requirements currently in effect under § 406.33(a)(1) through (6).
- At § 406.33(c)(2), we proposed to exclude additional months from the calculation of the LEP for enrollments on or after January 1, 2023.
- At § 408.24, we proposed to revise paragraph (a) to apply the existing Part B LEP calculation months and exceptions to individuals who satisfy the requirements of § 408.24 before January 1, 2023.
- At § 408.24, we proposed to require that for individuals who satisfy the requirements of § 408.24 after January 1, 2023, the months to be counted for calculating the Part B LEP begin with the end of the individual's IEP, and extends through the end of the month in which the individual enrolls.
- At § 408.24(b)(1), we proposed to continue to exclude certain months from the calculation of the LEP, consistent with the requirements currently in effect under § 408.24 (a)(1) through (10).
- At § 408.24(b)(2), we proposed to exclude additional months from the calculation of the LEP for enrollments on or after January 1, 2023.
- At § 406.34, we proposed to revise paragraph (a) to reflect the requirement that, for individuals reenrolling in premium Part A, the existing Part A LEP calculation requirements continue to apply to enrollments before January 1, 2023.
- At 406.34, we proposed to redesignate paragraph (e) as paragraph (f) and add new paragraph (e) to require that the months to be counted for calculating the Part A LEP begin with the end of the individual's IEP and extend through the end of the month in which the individual reenrolls, and we would continue to include the months currently specified in paragraphs (b) and (d) of this section, as applicable, and the months from the end of the first period of entitlement through the end of the month during the GEP in which the individual reenrolled.
- At § 406.34(e)(2), we proposed to exclude the months of non-coverage in accordance with an individual's use of an exceptional condition SEP under § 406.27.
- At § 408.24, we proposed to amend § 408.24, to revise newly redesignated paragraph (c) to apply the existing Part B LEP calculation months and exceptions for reenrollments to individuals who satisfy the requirements of § 408.24 before January 1, 2023.
- At § 408.24(d), we proposed to require that for individuals who satisfy the requirements of § 408.24 after January 1, 2023, the months to be counted for calculating the Part B LEP include the number of months elapsed between the close of the individual's IEP and the close of the month in which he or she first enrolled and the number of months elapsed between the individual's initial period of coverage and the close of the month in which he or she reenrolled (as well as the number of months elapsed between each subsequent period of coverage and the close of the month in which he or she reenrolled).
- At § 408.24(d)(2)(i), we proposed to continue to exclude certain months from the calculation of the LEP, consistent with the requirements currently in effect under § 408.24(a)(1) through (10) and also excluding months before April 1981 during which the individual was precluded from reenrolling by the two-enrollment limitation in effect before that date.
- At § 408.24(d)(2)(ii), we proposed that if an individual uses an exceptional condition SEP under § 407.23 any months of non-coverage would not be counted towards the calculation of the SEP, provided the individual enrolls within the duration of the SEP.

We received a couple of comments related to the proposed technical corrections for the LEP.

Comment: A few commenters expressed support specifically for the proposed changes to the LEP; however, the majority of that support was expressed in regards to how it related to the SEP proposals. Commenters stated that the proposed changes would ease the financial burden that Medicare premiums with added penalties can present for Medicare beneficiaries. To further reduce financial burdens, a commenter recommended that the LEP should reset once an individual reaches age 65.

Response: We appreciate the comments and support. We note that under 1837(g)(1) of the Act an individual will have a new IEP for each continuous period of Medicare eligibility as defined by section 1839(d) of the Act and upon attainment of age 65. Therefore, if an individual was subject to an LEP prior to attainment of age 65, the premium amount is reset without the LEP effective with the month of attainment of age 65. In addition, no months prior to age 65 should be counted in the calculation of a premium increase.

Based on analysis of the public comments, we will be finalizing these technical proposals related to LEP as proposed.

B. Proposals for Extended Coverage of Immunosuppressive Drugs for Certain Kidney Transplant Patients (§§ 406.13, 407.1, 407.55, 407.57, 407.59, 407.62, 408.20, and 423.30)

1. History and Definition of Benefit

In 1972, Congress enacted section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603), which amended section 226 of the Act to allow qualified individuals with ESRD [15] under the age of 65, to enroll in the federal Medicare health care program, beginning in 1973. These requirements are now codified in section 226A of the Act and implemented in our regulations at 42 CFR 406.13. As mentioned earlier, section 226A(a) of the Act provides that

[15] Under 42 CFR 406.13(b), ESRD means that stage of kidney impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.

certain individuals who are medically determined to have ESRD and apply for Medicare coverage are entitled to benefits under Medicare Part A and eligible to enroll in Part B. However, section 226A(b)(2) of the Act currently requires that an individual's entitlement under Part A and eligibility under Part B based on ESRD status ends with the 36th month after the month in which the individual receives a kidney transplant.

The termination of Medicare entitlement has led to some beneficiaries losing coverage of immunosuppressive drugs that transplant patients would still need. Per the 2018 US Renal Data System (USRDS) Annual Report, 32 percent of kidney transplant recipients ages 45–64 years old have no known or other creditable prescription drug coverage.[16] Section 402(a) of the CAA established an exception that permits certain beneficiaries who were kidney transplant patients to receive a limited Part B benefit effective January 1, 2023—covering only those immunosuppressive drugs described in section 1861(s)(2)(J) of the Act. Section 402(a) of the CAA also added section 1836(b) of the Act to support limited eligibility under Part B for beneficiaries whose entitlement to insurance benefits under Part A ends by reason of section 226A(b)(2). These individuals are eligible to enroll (or to be deemed enrolled) for the new Part B immunosuppressive drug benefit (herein referred to as the Part B–ID benefit).

Not all Medicare kidney transplant patients who lose entitlement to Part A coverage based on section 226A(b)(2), however, are eligible to enroll in the new Part B–ID benefit. The CAA provided that certain individuals are not eligible to enroll in the new program. In general, if the individuals are enrolled in certain specific forms of health insurance or other programs that cover immunosuppressive drugs, the individuals would not be eligible to enroll in the Part B–ID benefit. We discuss the excepted individuals and the specific forms of insurance and programs in greater detail in section II.B.2.b. of this final rule entitled ''Determination of Eligibility'' and in this final rule at § 407.55(b). Individuals who are seeking entitlement under the new Part B–ID benefit would also need to meet additional statutory criteria, as discussed in section II.B.2.b. of this final rule, and in this final rule at § 407.57.

Individuals enrolled in the new Part B–ID benefit would not receive Medicare coverage for any other items or services, other than coverage of immunosuppressive drugs. Section 402 of the CAA made conforming amendments to sections 1836, 1837, 1838, 1839, 1844, 1860D–1, 1902, and 1905 of the Act. We proposed to revise §§ 407.1, 408.20, 410.30, 423.30 and establish a new subpart D (§§ 407.55 through 407.62) in 42 CFR part 407, entitled *Part B Immunosuppressive Drug Benefit* to implement the new Part B–ID benefit. (We note that in discussing these changes in the proposed rule at 87 FR 25102 we erroneously referred to § 407.65 instead of § 407.62 and are now correcting that error.)

Specifically, we proposed the following:

- At § 407.1(a)(6) we proposed that, sections 1836(b) and 1837(n) of the Act will provide for coverage of immunosuppressive drugs as described in section 1861(s)(2)(J) of the Act under Part B beginning on or after January 1, 2023.
- At § 407.1(b) we proposed to retain the language that states that part 407 sets forth the eligibility, enrollment, and entitlement requirements and procedures for supplementary medical insurance at § 407.1(b)(1), including the reference to the rules governing premiums in part 408 of this chapter.
- At § 407.1(b)(2), we proposed to add language stating that this part also sets forth the eligibility, enrollment, and entitlement requirements and procedures for the immunosuppressive drug benefit provided for under sections 1836(b) and 1837(n) of the Act, including the short title for the Part B-immunosuppressive drug benefit (Part B–ID benefit).

We received comments from patient advocates, associations, States, health plans, and individuals offering broad support on our proposal to extend coverage of immunosuppressive drugs under Medicare Part B for eligible individuals whose benefits under Medicare based on ESRD would otherwise end the 36th month after the month an individual receives a kidney transplant. The comments on those proposals and our responses follow.

Comment: Many commenters expressed that this benefit was long-awaited and overdue, and they pointed out that the extended coverage of these drugs would help to prevent organ rejection in the post-transplant patient, and thus, will save lives and conserve Medicare resources. Other commenters stated that extending coverage of immunosuppressive drugs is clinically and economically advantageous given the evidence of significant improvement in quality of life, health outcomes, and cost savings on dialysis and hospitalization after a kidney transplant. A commenter pointed out that their State currently covers similar groups with State-only funds, but supports the creation of the Part B–ID benefit under Medicare. The commenter stated that this limited expansion of Medicare Part B is very worthwhile, and even though it is quite limited in scope, it has the potential to be lifesaving for ESRD patients.

Response: We appreciate the overwhelming support for our proposal and thank the commenters for their feedback. We agree with commenters that these changes are advantageous and will have a positive impact on this population.

Several commenters supported, but had concerns or requested clarifications about, the Part B–ID benefit, particularly about the scope of the Part B–ID benefit. Those comments and our responses are as follows.

Comment: A commenter stated that Congress adopted a narrowly crafted provision that will leave some patients still facing high, and possibly prohibitive, out-of-pocket costs, including co-insurance costs, as well as physician and lab services, since the patient is not allowed to have other insurance. Another commenter noted that, due to a potential lack of insurance coverage 36 months post-transplant, some patients have chosen not to seek a transplant due to the cost concerns after Medicare eligibility expires. The commenter stated that while the new benefit does not entirely address cost considerations that can inhibit transplant, it is important that transplant professionals are fully trained about the new benefit and that it is factored into assessments of patients' potential stewardship of a transplanted organ. A commenter suggested that this patient population would benefit from continuing to receive coverage for physical therapy under Medicare, as side effects from immunosuppressive drugs could have untoward effects on health, including weight gain, that could result in limitation of movement.

Response: We thank the commenters for their feedback. Section 402(a) of the CAA ensures that individuals without certain other types of coverage whose benefits under Medicare based on ESRD would otherwise end with the 36th month after the month in which the individual received a kidney transplant,

[16] United States Renal Data System: *2018 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States,* Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2018, from *https://cjasn.asnjournals.org/content/14/3/327.*

can maintain coverage for their immunosuppressive drugs essential to prevent rejection of their transplanted kidney. The benefit parameters of the statute are specific, and they do not allow coverage of other items and services. We refer the reader to section II.B.5 of this final rule for further information on education and outreach efforts for the implementation of the Part B–ID benefit.

We received numerous comments requesting clarification on, and recommendations for, coverage of various dosage forms of these drugs and other ancillary items that may be used in the post-transplant clinical setting. Those comments and our responses follow.

Comment: Several commenters questioned if the new benefit included coverage for compounded formulations of immunosuppressants (for example, a liquid formulation of an immunosuppressive medication not commercially available from the manufacturer that is prepared by a pharmacist), and a couple of commenters added that these formulations were frequently used in the treatment of pediatric kidney patients. Some commenters suggested that CMS consider coverage for mineral or electrolyte supplements, like magnesium, phosphorus, and bicarbonate related to post-transplant care that are particularly necessary in the care of pediatric patients. A commenter stated that transplant physicians must have uninterrupted access to all brand name drugs when he or she deems it necessary for a particular patient. A commenter questioned if drugs that are not categorized as immunosuppressive drugs, per se, such as anti-hypertensives, or drugs used for a patient's co-morbid conditions would be covered. A couple commenters inquired about the coverage of intramuscular (IM) and intravenous (IV) formulations, and asked if an administration fee is included in the Part B–ID benefit. A commenter stated that oral immunosuppressive drugs are clinically appropriate for the great majority of transplant recipients, but excluding coverage of the administration costs for those recipients who do require IV or IM drugs has the potential to impact access to an effective immunosuppressive drug regimen for patients who have no clinically appropriate alternative.

Response: Payment may be made for prescription drugs used in immunosuppressive therapy as described in federal regulations at 42 CFR 410.30(a). Further, § 410.30(c) states that drugs are covered under this provision irrespective of whether they can be self-administered. The lists of formulations in the proposed rule were examples only. Other types of formulations of immunosuppressive drugs defined in section 1861(s)(2)(J) of the Act as described above in the Summary section, including those that are not self-administered, would be covered and paid under this benefit. As set forth at 42 CFR 410.30(a) and described in § 50.5.1, Chapter 15 of the *Medicare Benefit Policy Manual,* covered drugs include those immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the FDA. Drugs with indications for other conditions not described in 42 CFR 410.30(a), such as mineral deficiencies or hypertension, would not be covered under the Part B–ID benefit. CMS does not maintain a list of drugs covered under this benefit; rather, the Medicare Administrative Contractors (MACs) are expected to maintain, a list of these drugs as set out in § 80.3, Chapter 17 of the *Medicare Claims Processing Manual.* The MACs are expected to keep informed of U.S. Food and Drug Administration (FDA) additions to the list of the immunosuppressive drugs and update guidance as applicable. For inquiries regarding specific drugs with regards to coverage under section 1861(s)(2)(J) of the Act, individuals may contact the DME MAC that processes the claim.

With regard to compounded formulations of immunosuppressants, such drugs are not approved for marketing by the FDA [17] and, therefore, are not covered under the Part B–ID benefit. With regard to the commenters' question if a fee is included for the administration of IM and IV formulations under the Part B–ID benefit, as we stated above, section 402(a) of the CAA provides that the benefits are solely for purposes of coverage of immunosuppressant drugs described in section 1861(s)(2)(J). We do not have flexibility to include payment for the administration of the product based on the statutory language of this benefit, as it only includes the actual drug products.

Comment: A couple commenters expressed concern about whether a beneficiary would have uninterrupted access to these drugs in the case of a beneficiary having issues arise at the pharmacy counter. A commenter stated that the reimbursement system must be fully in place by the January 1, 2023 effective date, otherwise, patients will be presented a bill or denied their prescription altogether. The commenter also expressed concerns in the case where a pharmacy cannot verify an individual patient's eligibility for the new benefit. A commenter questioned how the beneficiary will be assured uninterrupted access to their drugs in the case of data errors at the pharmacy counter. A commenter urged CMS to make guidance and any related resources available to stakeholders including plans, providers, and beneficiary advocates as soon as possible given the January 1, 2023 effective date for key provisions in the rule. The commenter stated that technical guidance is needed to understand if and how entitlement for the Part B–ID benefit would be reflected in the Medicare Advantage Prescription Drug (MARx) system, and also requested that technical assistance be provided on the transaction reply codes that will be used in the MARx system. A commenter urged CMS to consider having a dedicated pharmacy hotline during the first few months so that questions and concerns by pharmacists can be resolved in real time. Commenters requested that CMS take steps to ensure that there is a safety net, and they recommended that CMS put in place a system that ensures access to medications while back-end determinations of payment responsibility are sorted out.

Response: We thank the commenters for their feedback and concern. In anticipation of the January 1, 2023 effective date for the Part B–ID benefit, Medicare payment systems, including the Common Working File (CWF), ViPS Medicare System (VMS), the Multi-Carrier System (MCS), and the Federal Intermediary Standard System (FISS) are being modified to properly process claims submitted for immunosuppressive drugs under the Part B–ID benefit. Other entities that will assist with claims processing, including the Medicare Part A and Part B MACs and the Durable Medical Equipment MACs, have also been engaged in the implementation efforts. Additionally, modifications are being made to ensure that eligible beneficiaries are accurately recognized within these systems. All operational and systems changes are slated to be completed prior to the January 1, 2023 effective date. Therefore, we expect beneficiaries' access will be uninterrupted as we implement this new benefit.

With respect to the public comment related to the MARx system, that system is used for beneficiary eligibility and

[17] *https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.*

enrollment for Medicare Part C and Part D plans, and cannot be used by pharmacy providers to verify eligibility for the Part B–ID benefit. We do not expect that there will be a dedicated pharmacy hotline specific to the Part B–ID benefit; however, Medicare providers, including pharmacists and suppliers, can check patient eligibility, (as well as billing and other pertinent information) by either utilizing their MAC online provider portal or Interactive Voice Response (IVR) system, the Health Insurance Portability and Accountability Act Eligibility Transaction System (HETS), or their billing agencies, clearinghouses, or software vendors. For further information, please see the Medicare Learning Network instructions here: *https://www.cms.gov/files/document/checking-medicare-eligibility.pdf.* If a beneficiary has an issue at the pharmacy counter they may call 1–800–MEDICARE, and the 1–800–MEDICARE Call Center will troubleshoot as they currently do with existing provider access concerns. If the issue cannot be resolved, it will be escalated to the CMS Offices of Hearings and Inquiries via the current Ombudsman escalation process.

We note that individuals who enroll in the Part B–ID benefit will be provided with a new Medicare card that will include the specific language that describes the benefit. These beneficiaries will also receive a notice with that card which provides information on the benefit, including use of their prior and current Medicare cards, and contact information for further questions or concerns. We plan to educate pharmacies and other health care providers later this year on changes related to the Part B–ID benefit patient eligibility transaction that will reflect immunosuppressive drug coverage, including the eligibility inquiry transaction reply. Pharmacies should contact their MAC for claims processing technical assistance as they currently do for other claims processing issues. Further information on education and outreach to inform beneficiaries and stakeholders about the Part B–ID benefit is discussed in section II.B.5 of this final rule.

Medicare regulations do not require a pharmacist to provide minimal amounts of immunosuppressive therapy if the beneficiary's coverage cannot be verified; this would be up to the established process at the individual pharmacy.

Comment: A commenter stated that the proposed rule referred to ''successful'' kidney transplantation. The commenter recommended striking the term ''successful'' and simply stating that the new Part B–ID benefit is extended to kidney transplant recipients.

Response: We thank the commenter for their feedback and have removed successful from the description used in this final rule as official eligibility criteria. The term ''successful'' in the preamble of the proposed rule was used, generally, to describe a person whose Medicare Part A enrollment terminated 36-months after transplant and whose transplanted kidney functions to the point where the individual does not need a regular course of dialysis to sustain life. If the person's transplant was not successful, the patient would likely require a regular course of dialysis to sustain life, and eligibility for Medicare coverage under Part A and Part B based on ESRD would continue.

2. Part B–ID Benefit Eligibility, Enrollment, Entitlement, and Termination

a. Eligibility for the Part B–ID Benefit

Section 402(a)(2) of the CAA adds section 1836(b) of the Act, which establishes specific eligibility criteria for the Part B–ID benefit. Subject to exceptions, new section 1836(b)(1) of the Act provides that individuals whose entitlement to insurance benefits under Part A ends (whether before, on, or after January 1, 2023) by reason of section 226A(b)(2), and who meet certain additional requirements, would be eligible to enroll (or to be deemed enrolled) in Part B solely for purposes of coverage of immunosuppressive drugs in accordance with section 1837(n) of the Act. The principal limitations on eligibility for the Part B–ID benefit are set out in new section 1836(b)(2) of the Act. Under section 1836(b)(2)(A) of the Act, individuals enrolled in certain other types of health coverage would not be eligible for the Part B–ID benefit.

b. Determination of Eligibility

Section 1836(b)(2)(B)(i) of the Act requires the Secretary, in coordination with the Commissioner of Social Security (Commissioner), to establish a process for determining whether an individual who is to be enrolled, or deemed to be enrolled, in the Part B–ID benefit meets the requirements for such enrollment, including the requirement that the individual not be enrolled in other health coverage that would make them ineligible for the Part B–ID benefit under 1836(b)(2)(A) of the Act.

In order for an individual to be enrolled in the Part B–ID benefit, section 1836(b)(2)(B)(ii)(I) of the Act requires that an individual provide to the Commissioner an attestation that they are not enrolled and do not expect to enroll in the excepted coverage, as described in section II.B.2.a. of this final rule (''Eligibility for the Part B–ID Benefit''), that would make the individual ineligible for the Part B–ID benefit under section 1836(b)(2)(A) of the Act. Section 1836(b)(2)(B)(ii)(II) of the Act requires that the individual notify SSA within 60 days of enrollment in such excepted coverage. Based on these requirements, we proposed at § 407.59(a) and (b), that all prospective enrollees in the Part B–ID benefit must provide to the Commissioner, in either a verbal attestation or signed paper form, an attestation that the individual is not enrolled and does not expect to enroll in other health coverage that would make the individual ineligible for the Part B–ID benefit, and that the individual agrees to notify the Commissioner within 60 days of enrollment in such other coverage as described in § 407.55(b).

We proposed that beneficiaries will be able to primarily use a verbal (telephonic) attestation as part of enrolling in the Part B–ID benefit. Generally, for the verbal attestation, an individual would contact SSA, and an SSA representative, using a standard script, will convey the requirements to the individual that are in the CMS–10798 [18] attestation form, described in § 407.59 of this final rule. The individual will then attest that the individual does not have coverage under any of the specified health programs or insurance. The individual will also affirm that the statement provided was true and correct and that the individual acknowledged that there may be criminal penalties for making a false statement for purposes of obtaining these Medicare benefits. After the individual provides the oral attestation, the SSA representative will document the content of the call, and the document will be retained as required under SSA processes. We also proposed that individuals would be permitted to provide the attestation in writing with a pen-and-ink signature, if they choose to do so. Under our proposal, individuals could download a PDF-fillable version of an attestation form from SSA or CMS websites to print, sign, and mail to SSA, or to call SSA to request the form in hard copy.

As mentioned previously, we proposed to establish the eligibility criteria for the Part B–ID benefit in new § 407.55, entitled ''Eligibility to enroll.'' Specifically, in § 407.55(a), we proposed

[18] *Medicare.gov/forms-help-other-resources/medicare-forms.*

that an individual would be eligible to enroll in, be deemed enrolled, or re-enroll in the Part B–ID benefit if their Part A entitlement ends at the end of the 36th month after the month in which the individual received a kidney transplant, as set out under revised § 406.13(f)(2), and discussed in section II.B.5 of this final rule.

The types of coverage that would make an individual ineligible for the Part B–ID benefit are specified in section 1836(b)(2)(A)(i) through (v) of the Act. Specifically, the Act requires that individuals shall not be eligible for enrollment in the Part B–ID benefit during any period the individual is:

- Enrolled in a group health plan or group or individual health insurance coverage, as such terms are defined in section 2791 of the Public Health Service Act;
- Enrolled for coverage under the TRICARE for Life program under section 1086(d) of title 10, United States Code;
- Enrolled under a State plan (or waiver of such plan) under title XIX of the Act and is eligible to receive benefits for immunosuppressive drugs described in section 1836(b) of the Act under such plan (or such waiver);
- Enrolled under a State child health plan (or waiver of such plan) under title XXI of the Act and is eligible to receive benefits for such drugs under such plan (or such waiver); or
- Enrolled in the patient enrollment system of the Department of Veterans Affairs established and operated under section 1705 of title 38, United States Code and is either of the following:

++ Is not required to enroll under section 1705 of such title to receive immunosuppressive drugs described in section 1836(b) of the Act; or

++ Is otherwise eligible under a provision of title 38 of the United States Code (other than section 1710), to receive immunosuppressive drugs described in section 1836(b) of the Act.

We proposed regulation text at § 407.55(b) that would mirror those requirements, as set out in sections 1836(b)(2)(A)(i) through (v) of the Act. Section 1836(b)(2) of the Act contains specific exceptions that prevent individuals from enrolling in the Part B–ID benefit. For some of those provisions, section 402 of the CAA includes an additional limitation that the coverage must include coverage of immunosuppressive drugs. For other coverage, the statute does not include this limitation. When specific restrictions are included in one section of a statute but not in another, we presume that the language of the statute is intentional and deliberate with respect to adding the limitations. This is sometimes called the negative implication canon or *expessio unius est exclusion alterius.*

c. Enrollment in the Part B–ID Benefit

Section 1837(n)(1) of the Act states that any individual who is eligible for coverage of immunosuppressive drugs under section 1836(b) of the Act, that is, whose entitlement for hospital insurance benefits under part A ends by reason of section 226A(b)(2) may enroll or be deemed to have enrolled in the Part B–ID benefit as established in regulations and during an enrollment period described in statute. We proposed in § 407.57(d) that, to enroll in the Part B–ID benefit, an individual must submit the required attestation as described in § 407.59. We also proposed in § 407.55(c) that, if SSA denies an individual's enrollment in the Part B–ID benefit, the individual will be afforded an initial determination entitlement appeal as described in § 405.904(a)(1). This will ensure that the beneficiary's statutory and due process rights will be adequately protected.

We proposed to establish the provisions relating to enrollment and the entitlement to the Part B–ID benefit in new § 407.57, titled ''Part B–ID benefit enrollment.'' Specifically, we proposed at § 407.57(a) that an individual whose Part A entitlement ends at the end of the 36th month after the month in which the individual received a kidney transplant, on or after January 1, 2023, is deemed to have enrolled into the Part B–ID benefit effective the first day of the month in which the individual first satisfies the eligibility requirements proposed at § 407.55, and provides the attestation required in proposed § 407.59, prior to the termination of their Part A benefits.

In accordance with new subsections 1837(n)(2) and (3) of the Act, certain individuals have an ongoing opportunity to enroll in the Part B–ID benefit regardless of whether their entitlement under Part A ended before or after January 1, 2023. Therefore, we proposed at § 407.57(b) that an individual whose Part A entitlement ends in accordance with revised § 406.13(f)(2) (as discussed in section II.B.5. of this final rule), and who meets the Part B–ID benefit eligibility requirements at § 407.55 and provides the attestation required in § 407.59, may enroll in the Part B–ID benefit as follows:

- An individual whose entitlement ended prior to January 1, 2023 may enroll in the Part B–ID benefit beginning on October 1, 2022 or later.
- An individual whose entitlement ends on or after January 1, 2023 can enroll at any time after such entitlement ends.

We further proposed at § 407.57(c) that an individual who had previously enrolled in the Part B–ID benefit but whose participation in the benefit was terminated may re-enroll in the Part B–ID benefit at any time if they meet the eligibility requirements at § 407.55 and provides the attestation required in § 407.59. There are no late enrollment penalties assessed, regardless of when an individual enrolls or disenrolls from the benefit.

d. Effective Date of Entitlement

Provided the individual meets the eligibility requirements described at § 407.55 and provides the attestation as required under § 407.59, we proposed the following entitlement dates in § 407.57(e):

- For individuals whose Medicare Part A entitlement based on ESRD status ends on or after January 1, 2023, and who submit the attestation required under § 407.59 before the end of the 36th month after the month in which they receive a kidney transplant, their entitlement begins with the month their Part A benefits under section 226A of the Act would end.
- For individuals who do not provide an attestation as part of the enrollment process for the Part B–ID benefit before their Part A entitlement under section 226A of the Act ends, but later provides an attestation, their entitlement begins with the month following the month in which the individual provides the attestation required in § 407.59.
- For individuals whose entitlement ended prior to January 1, 2023 and who submit an attestation as part of the enrollment process from October 1, 2022 through December 31, 2022, their entitlement begins January 1, 2023.

e. Termination of the Part B–ID Benefit

Under sections 1838(b) and (h)(4) of the Act, individuals are not required to enroll or remain enrolled in the Part B–ID benefit. Individuals enrolled in the Part B–ID benefit can terminate their enrollment in the Part B–ID benefit by notifying SSA that they no longer wish to participate in the Part B–ID benefit. SSA would also terminate the Part B–ID benefit under certain conditions. Consistent with these requirements, we proposed in new § 407.62, ''Termination of coverage,'' that the effective date of the termination of an individual's entitlement under the Part B–ID benefit will depend upon the conditions of his or her termination, as described in this section.

We proposed the following requirements related to termination of the Part B–ID benefit:

- Under proposed § 407.62(a)(1), when an individual enrolls in such other health coverage that would make them ineligible for the Part B–ID benefit as set out in § 407.55(b) and notifies the Commissioner of this health coverage consistent with § 407.59(b), their Part B–ID benefit would be terminated effective the first day of the month after the month of notification.
- We proposed in § 407.62(a)(1) that when an individual enrolls in other coverage and provides notification consistent with § 407.59(b), their enrollment in the Part B–ID benefit would end effective the first day of the month after the month they provide the required notification. We also proposed at § 407.62(a)(1) that an individual may request a different, prospective termination date for the Part B–ID benefit to align with the coverage period under the other insurance plan or government program.
- We proposed in § 407.62(a)(2) that for an individual who enrolls in the Part B–ID benefit, but who subsequently enrolls in other health coverage as described in § 407.55(b) but does not notify SSA within 60 days consistent with § 407.59(b), the individual's Part B–ID enrollment would be terminated effective the first day of the month after the month in which SSA determines the individual is enrolled in health coverage described in § 407.55(b).
- We proposed in § 407.62(f) that, if an individual is involuntarily disenrolled from the Part B–ID benefit based on § 407.62(a)(2), (b) or (c), they will be permitted an initial determination appeal as outlined in § 405.904(a)(1), which is consistent with existing requirements applicable to Part B coverage.
- Consistent with existing requirements applicable to Part B benefits at § 407.27(a), which state that entitlement to Part B benefits ends on the last day of the month in which an individual dies, we proposed that entitlement to the Part B–ID benefit would end on the last day of the month in which the individual dies under new proposed § 407.62(b).
- We proposed at § 407.62(c) that termination of the Part B–ID benefit for individuals who fail to pay their Part B–ID benefit premiums would end as set forth in 42 CFR part 408. An individual will receive a grace period in which overdue premiums may be paid and coverage continued.
- We proposed at new § 407.62(d) that an individual may request disenrollment at any time by contacting SSA to inform them that they no longer want to be enrolled in the Part B–ID benefit. Such individuals' enrollment would end with the last day of the month in which the individual provides the disenrollment request.
- We proposed that an individuals' entitlement to the Part B–ID benefit will terminate effective the last day of the month prior to the month in which the individual becomes entitled to Medicare based on either age, disability, or ESRD under new proposed § 407.62(e).

We received numerous comments on our proposed requirements related to eligibility, enrollment, effective dates of coverage, and termination of the Part B–ID benefit. Those comments received and our responses are as follows.

Comment: Many commenters supported CMS' approach to allow individuals to use various methods to attest to their eligibility and enroll in the Part B–ID benefit. A commenter stated that the options that CMS proposed did not appear to be burdensome. Many commenters supported the verbal attestation, citing that it was simple and efficient, and it would avoid potential delays with signing and mailing statements that could result in delays in accessing needed immunosuppressive drugs. A commenter stated that a written approach would alleviate long wait times on SSA phone lines, but supported both verbal and written options. A commenter strongly opposed use of the written-only option for submitting an attestation. Other commenters recommended that CMS consider additional methods of attestation, particularly electronic submission, fax, or other signed documents.

A commenter stated that CMS took an open-minded and forward-thinking approach to attestation and enrollment in the Part B–ID benefit, and they were encouraged by the Agency's expedient use of the Executive Order (E.O.) on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government. The commenter also stated that CMS' plans for defining a suitable process and criteria for beneficiary enrollment in the Part B–ID program is simple, straightforward, and customer-centric.

Response: We appreciate the feedback we received on our Part B–ID eligibility and enrollment proposals. CMS will be partnering with SSA to employ both a verbal and written attestation process for an individual to enroll in the Part B–ID benefit. An individual will be able to contact SSA to verbally provide an attestation to enroll in the Part B–ID benefit, or they can download a PDF-fillable form from the CMS or SSA website, complete the form, and mail to SSA. If an individual does not have internet access, an SSA representative can download the form and mail the form to the caller to complete and mail. At this time, forms will be accepted via U.S. mail delivery, but SSA plans to include an option to receive completed forms via facsimile (fax) in the future. We are also continuing to explore the future development of an electronic process to submit the attestation. To provide for flexibility for other attestation methods in the future, we are revising § 407.59 to state that an individual must attest to SSA in either a verbal attestation, signed paper form provided by SSA, by electronic submission, or fax under procedures determined by SSA. This will give SSA the flexibility to implement a fax or electronic attestation process in the future, when these options become available.

Comment: A commenter stated that submission of an attestation and confirmation of an individual's eligibility will be sufficient for SSA to enroll individuals in the Part B–ID benefit. The commenter expressed satisfaction with CMS' plan for monitoring and oversight that will enable it to address any concerns that may arise. Another commenter stated that we proposed that all prospective Part B–ID beneficiaries provide proof they lack insurance coverage of immunosuppressive drugs.

Response: In the proposed rule, we did not propose that individuals would have to provide proof that they do not have coverage of immunosuppressive drugs. In order for an individual to be enrolled in the Part B–ID benefit, the statute requires that an individual submit an attestation to SSA that they are not enrolled in, and do not expect to enroll in, coverage under any of the specified health programs or insurance described in law that make an individual ineligible for the Part B–ID benefit. It also requires that the individual notify SSA within 60 days of enrollment in the coverage described in law. We proposed that an individual would be able to provide this attestation verbally or in writing. We agree with the first commenter that submission of an attestation and confirmation of an individual's eligibility from their previous entitlement to Medicare based on ESRD is sufficient for SSA to enroll individuals in the Part B–ID benefit. As we stated in the proposed rule, we will monitor developments in the Part B–ID benefit program and take appropriate action to address any potential areas of concern, including with respect to

inaccurate attestations or other conditions involving ineligible individuals enrolling or remaining enrolled in the Part B–ID benefit. We will continue to evaluate opportunities to enhance our oversight to ensure compliance with the eligibility requirements on an ongoing basis.

Comment: A commenter questioned if an individual needs an SEP to enroll in the Part B–ID benefit.

Response: Individuals do not need an SEP to enroll in the Part B–ID benefit. Unlike Part B (or other parts of the Medicare program) where individuals can only enroll during an enrollment period, if an individual is eligible for the Part B–ID benefit, they can enroll at any time and will not be subject to an LEP for months of non-coverage. Because individuals can gain or lose health coverage throughout their lifetime, it is important to extend flexibility to those needing coverage of their immunosuppressive drugs.

A couple commenters provided feedback on the effective date of coverage for the Part B–ID benefit.

Comment: A commenter stated that, in order to prevent kidney allograft rejection and maintain kidney allograft function, immunosuppressive drugs must be taken every day, without exception. Therefore, it is essential that Part B–ID enrollment processes are straightforward, the steps are efficient, and that coverage be activated immediately upon enrollment (that is, and not the first day of the month that follows). Another commenter stated they supported CMS granting the Part B–ID benefit for eligible individuals in 2022.

Response: We appreciate the commenter's concern about an individual having uninterrupted access to these important drugs. However, enrollment in the Part B–ID benefit is a process—the individual has to submit an attestation; then SSA needs to verify the eligibility for the benefit and complete all operational processes established in SSA policy for enrollment. Based on reasonable timeframes to accomplish these actions, it would not be feasible for an individual to gain entitlement to the Part B–ID benefit on the actual date that the individual begins the process of enrollment. Also, Medicare coverage across programs starts on the first of the month, and premiums are based on a whole month of enrollment.

An eligible individual will be deemed to be enrolled in the Part B–ID benefit if they complete a timely attestation prior to the end of their 36th month of Medicare coverage based on ESRD, which ensures that the individual has seamless coverage of immunosuppressive drugs. To clarify, eligible individuals will be able to start the enrollment process in late 2022, but the Part B–ID benefit will not be effective until January 1, 2023.

A couple of commenters provided feedback on the proposed appeal and re-enrollment process for the Part B–ID benefit.

Comment: A couple commenters supported that individuals should be afforded an appeal process if their enrollment in the Part B–ID benefit is denied or terminated. Commenters also supported the re-enrollment option for individuals that have, and then lose, other comprehensive coverage. A couple of commenters also supported that no late enrollment penalties would be assessed for re-enrollment.

Response: We appreciate the support for our proposal to provide initial determination entitlement appeals upon denial of enrollment in or termination from the Part B–ID benefit. This ensures that the beneficiary's statutory and due process rights will be adequately protected. Also, we appreciate the support for our re-enrollment policy, as we understand that individuals can come in and out of health coverage during their lifetime. We agree that the re-enrollment option will provide a safety net for these important drugs, without the concern of a penalty, and we thank the commenters for their support of the late enrollment penalty policy.

We received several comments asking for clarification as to what individuals or groups were eligible for the Part B–ID benefit. Those comments and responses are as follows.

Comment: A commenter questioned whether CMS misinterpreted the statute with respect to the exception for eligibility under the new Part B in section 1836(b)(2) of the Act. The statute expressly provides that:

(2) EXCEPTION IF OTHER COVERAGE IS AVAILABLE.—

(A) IN GENERAL.—An individual described in paragraph (1) shall not be eligible for enrollment in the program for purposes of coverage described in such paragraph with respect to any period in which the individual, as determined in accordance with subparagraph (B)—

(i) is enrolled in a group health plan or group or individual health insurance coverage, as such terms are defined in section 2791 of the Public Health Service Act;

(ii) is enrolled for coverage under the TRICARE for Life program under section 1086(d) of title 10, United States Code;

(iii) is enrolled under a State plan (or waiver of such plan) under title XIX and is eligible to receive benefits for immunosuppressive drugs described in this subsection under such plan (or such waiver);

(iv) is enrolled under a State child health plan (or waiver of such plan) under title XXI and is eligible to receive benefits for such drugs under such plan (or such waiver); or

(v)(I) is enrolled in the patient enrollment system of the Department of Veterans Affairs established and operated under section 1705 of title 38, United States Code;

(II) is not required to enroll under section 1705 of such title to receive immunosuppressive drugs described in this subsection; or

(III) is otherwise eligible under a provision of title 38, United States Code, other than section 1710 of such title to receive immunosuppressive drugs described in this subsection.

(B) ELIGIBILITY DETERMINATIONS.—

(i) IN GENERAL.—The Secretary, in coordination with the Commissioner of Social Security, shall establish a process for determining whether an individual described in paragraph (1) who is to be enrolled or deemed to be enrolled in the medical insurance program described in such paragraph meets the requirements for such enrollment under this subsection, including the requirement that the individual not be enrolled in other coverage as described in subparagraph (A).

The commenter suggested that, under our proposed interpretation, an individual would not be entitled to Part B–ID even if the excepted health plan did not expressly cover post-transplant immunosuppressive therapy. The commenter also suggested that the statutorily identified excepted plans may not be as robust as Medicare Part B–ID, but the individuals would still be precluded from enrolling in Part B–ID. The commenter stated that transplant recipients with coverage other than Title XIX would be disadvantaged. The commenter also stated that they doubted that is what Congress set out to do and requested that CMS reconsider its interpretation. Another commenter stated that, for other coverage to render a patient ineligible for the Part B–ID benefit, the ''other'' coverage must cover immunosuppressive drugs.

Response: We disagree with the commenter's suggestion that our interpretation of the statute is incorrect. We trust that our interpretation of the statute, as described in the proposed rule(87 FR 25104), and in this final rule, is correct because it is consistent with

the plain language of the statute. If an individual has coverage that satisfies the conditions in section 1836(b)(2)(A)(1) of the Act, that individual is not eligible for enrollment in the Part B–ID benefit, even if the program does not expressly include coverage for immunosuppressive drugs. As we noted in the preamble to the proposed rule, only some of the programs identified in section 1836(b)(2)(A) of the Act expressly require that the patient have access to immunosuppressive drug coverage while other programs identified in section 1836(b)(2)(A) of the Act do not expressly require access to immunosuppressive drug coverage.

Comment: Another commenter stated that the Part B–ID benefit was for individuals whose Medicare eligibility has terminated after a kidney transplant and who do not have other access to coverage of such medication.

Response: The actual language of the statute is more precise than the commenter's general summary. To clarify, an individual's enrollment in any of the coverage specified under section 1836(b)(2)(A) of the Act would make the individual ineligible for the Part B–ID benefit.

Comment: Several commenters questioned Part B–ID eligibility for other populations/groups such as those in Indian Health Service (IHS), those who receive State kidney disease financial assistance, and those enrolled in programs such as a Medicaid program with limited coverage (for example, mental health coverage only). Another commenter inquired if enrollment in a charity program (for example, manufacturer-based free drug programs) constitutes ''a program that covers immunosuppressive drugs'' and questioned if it would preclude eligibility for the new Part B–ID benefit.

Response: As noted in the response to the previous comment, eligibility for the Part B–ID benefit is limited, but only individuals who are covered only under one of the express statutory provisions are excluded from eligibility. Generally, the programs that were identified by these commenters would not prevent an individual from enrolling in Part B–ID. Thus, if an individual only has coverage from the Indian Health Service (IHS), State kidney disease financial assistance, or charity/manufacturer assistance programs, the individual could still be eligible for Part B–ID. The same is true for an individual that is only eligible for restricted eligibility under Medicaid and CHIP, if the limited coverage does not make the individual eligible to receive benefits for immunosuppressive drugs.

Comment: A commenter questioned if an individual is eligible for the Part B–ID benefit if they were not entitled to Medicare at the time of their kidney transplant.

Response: Eligibility for the Part B–ID benefit in section 1836(b) does not depend on whether the individual was entitled to Medicare at the time of the kidney transplant. Instead, eligibility is based on whether the individual's Medicare coverage under Part A ended after the kidney transplant under section 226A(b)(2) of the Social Security Act.

Comment: A commenter requested that CMS clarify the status of the Part B–ID benefit with regard to beneficiaries who received pre-emptive transplants.

Response: An individual who has a pre-emptive kidney transplant, and meets the requirements for entitlement to Medicare Part A by reason of section 226A(b)(2),) of the Act, as outlined in at § 406.13(c), and, whose entitlement to insurance benefits under Medicare Part A ends (whether before, on, or after January 1, 2023) by reason of section 226A(b)(2) of the Act, would be eligible for Part B–ID, as long as they meet all other requirements for entitlement to the Part B–ID benefit.[19]

Comment: A commenter questioned if MA plans will have any role in the coverage of Part B–ID benefits. The commenter stated it was unclear as to whether those ESRD-eligible beneficiaries who are enrolled in MA plans and who have no alternative sources of coverage will have the opportunity to remain enrolled in these plans past 36 months post-transplant solely for the purpose of obtaining immunosuppressive drug coverage.

Response: Individuals enrolled in MA plans are not eligible for the Part B–ID benefit. Individuals who have Medicare Part A and B, regardless of the basis for which they are entitled to Medicare coverage (age, disability, ESRD, etc.), can enroll in an MA plan. However, if an individual has Medicare based on ESRD, and that individual's Medicare entitlement ends the 36th month after the month in which they receive a kidney transplant, they no longer have Medicare Part A and B, and therefore, are not eligible to remain in the MA plan. Individuals who meet all of the requirements to enroll in the Part B–ID benefit are also not eligible to enroll in or receive immunosuppressive drugs from an MA plan.

3. Ensuring Coverage Under the Medicare Savings Programs

The MSPs includes three primary[20] Medicaid eligibility groups that cover the Medicare Part A and/or B premiums and sometimes cost sharing for over 10 million low-income individuals and are defined at sections 1905(p)(1) and 1902(a)(10)(E) of the Act. One MSP eligibility group is the Qualified Medicare Beneficiary (QMB) group, which provides medical assistance through coverage of Medicare Part A and B premiums and cost sharing for certain individuals that meet specific requirements. In general, the individual must have income that does not exceed 100 percent of the federal poverty line (FPL) and resources that do not exceed 3 times the limit for SSI with adjustments for inflation as described in section 1905(p)(1) of the Act. A second MSP eligibility group is the Specified Low-Income Medicare Beneficiary (SLMB) group, which provides medical assistance through coverage of Part B premiums for individuals who would otherwise be eligible in the QMB eligibility group, except that their income exceeds 100 percent of the FPL and is below 120 percent of the FPL as defined at section 1902(a)(10)(E)(iii) of the Act. A third MSP eligibility group is the Qualifying Individuals (QI) group, which provides medical assistance of coverage of Part B premiums for individuals who would otherwise be eligible in the QMB group, except that their income exceeds 120 percent of the FPL and is below 135 percent of the FPL as defined at section 1902(a)(10)(E)(iv) of the Act. Federal statute does not allow States to implement MSP eligibility criteria (that is, income and resource limits and methodologies) that are more restrictive than those federal baselines. However, through authority granted by section 1902(r)(2) of the Act, many States have elected to implement income and/or resource methodologies that are more generous than the federal baselines for QMB, SLMB, and QI.

As a result of changes made under section 402(f) of the CAA, low-income individuals who are entitled to Medicare based on enrollment in the Part B–ID benefit may also be eligible

[19] According to Mayo Clinic, ''A preemptive kidney transplant is when you receive a kidney transplant before your kidney function deteriorates to the point of needing dialysis to replace the normal filtering function of the kidneys.''

https://www.mayoclinic.org/tests-procedures/preemptive-kidney-transplant/pyc-20384830.

[20] There is a fourth and much smaller MSP eligibility group that is the Qualified Disabled Working Individuals (QDWI) group, which provides medical assistance of coverage of Part A premiums for individuals who are entitled to Part A under section 1818A of the Act, and with income that does not exceed 200 percent of the FPL and whose resources do not exceed twice the maximum amount permitted under the SSI program. Section 402 of the CAA does not apply to QDWIs.

for enrollment in QMB, SLMB, or QI eligibility groups for payment of some or all of their Part B–ID benefit premiums and cost sharing.

Section 402(f) of the CAA revised section 1905(p)(1)(A) of the Act to change the definition of QMB to allow for individuals enrolled in the Part B–ID benefit to be eligible for medical assistance through Medicare cost sharing as QMBs if they otherwise meet the income and resource limits established at 1905(p)(1)(B) and (C) of the Act. The CAA also made similar changes under section 1902(a)(10)(E)(iii) and (iv) of the Act to make medical assistance available for Medicare cost sharing for Part B–ID benefit enrollees who qualify for the SLMB and QI eligibility groups. These changes would allow individuals enrolled in the Part B–ID benefit to attain eligibility for these MSPs for payment of their Part B–ID benefit premium and cost sharing for QMBs, and for payment of their Part B–ID benefit premium as SLMBs and QIs, if such beneficiaries also meet the relevant income and resource criteria. We proposed to codify this expansion of MSPs to apply to the Part B–ID benefit at new § 435.123.

Under sections 1905(p)(1) and 1902(a)(10)(E) of the Act, as modified by section 402(f) of the CAA, individuals eligible for the Part B–ID benefit could become enrolled in MSPs for payment of the Part B–ID benefit (MSP Part B–ID) through two paths on or after January 1, 2023. First, individuals could enroll in the Part B–ID benefit and newly apply for Medicaid and be determined eligible for the QMB, SLMB, or QI eligibility groups by their State. Second, individuals who are enrolled in an MSP eligibility group and whose Medicare eligibility is based on ESRD can transition to an MSP based on Part B–ID (MSP Part B–ID) the month after 36 months after transplant if they enroll in the Part B–ID benefit under certain conditions. In order to transition to MSP Part B–ID under this latter condition, the individual must (a) provide an attestation to SSA to be deemed to enroll in the Part B–ID benefit by the end of the 36th month after the month in which they receive a kidney transplant in accordance with the attestation requirements in section 1836(b)(2)(B) of the Act and (b) continue to meet the other eligibility criteria for an MSP eligibility group described in section 1905(p)(1), 1902(a)(10)(E)(iii), or (iv) of the Act. We focused our discussion on the second path for MSP Part B–ID enrollment, noting our aim of promoting continuity of coverage for individuals who are enrolled in an MSP eligibility group and whose Medicare eligibility based on ESRD is ending and that multiple variables can affect whether an individual can seamlessly transition to the MSP Part B–ID benefit.

In the proposed rule (87 FR 25107), we confirmed that loss of Medicare entitlement based on ESRD status constitutes a change in circumstances that may affect ongoing Medicaid eligibility. Accordingly, we stated that, under § 435.916(d)(1), State Medicaid agencies are required to promptly redetermine an individual's eligibility for Medicaid whenever it receives information about an individual's loss of Medicare entitlement based on ESRD status.

We explained that individuals who remain or are determined eligible for full-benefit Medicaid after this redetermination process would not be eligible for the Part B–ID benefit, because all States currently opt to cover immunosuppressive drug coverage for all full-benefit Medicaid eligibility groups and, by virtue of having such drug coverage under Medicaid, they would be ineligible according to section 1836(b)(2)(A)(iii) of the Act.

On the other hand, we explained that if the individual is not eligible for Medicaid on any basis, the State is required to screen the individual for potential eligibility for other insurance affordability programs as defined in § 435.4 in accordance with § 435.1200(e), as required under § 435.916(f). This would include referring the individual to an Exchange to determine whether the individual is eligible for enrollment in a Qualified Health Plan with advance premium tax credits (APTCs), cost sharing reductions (CSRs) or both as described in § 435.4. We also encouraged States to inform individuals who do not qualify for full-benefit Medicaid or the Exchange with either APTCs or CSRs of the MSP Part B–ID benefit as part of the redetermination process. Specifically, States can refer individuals to engage with SSA, State Health Insurance Assistance Programs (SHIPs), and beneficiary advocacy groups, among others, to obtain information about the Part B–ID benefit.

In order to prevent gaps in coverage of critical immunosuppressive medication when individuals transition off Medicare entitlement based on ESRD status, for partial-benefit Medicaid beneficiaries (beneficiaries enrolled in an MSP and not full-benefit Medicaid), we strongly recommended that States conduct early advance redeterminations under § 435.916(d) before individuals' Medicare eligibility based on ESRD status ends. We anticipated this early redetermination process, along with planned CMS outreach efforts for beneficiaries and multiple external partners, would improve the customer service experience of kidney transplant recipients, consistent with *the Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government. We also stated our belief that these measures* would have a positive health equity impact consistent with the *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.* Finally, by helping to avoid gaps in Medicaid and Marketplace coverage, we noted that these efforts are consistent with the *Executive Order on Strengthening Medicaid and the Affordable Care Act.*

In general, individuals with ESRD are more likely to be from racial or ethnic minority groups.[21] Additionally, individuals who are younger, poorer, and less educated have more difficulty affording transplant medication, which has led to lower rates of graft survival among those populations.[22] Making immunosuppressive drugs more affordable to individuals through MSPs would improve lower income individuals' access to immunosuppressive drugs critical to prevent transplant failure. For a more comprehensive discussion of how the Medicaid redetermination process will operate for both full-benefit and partial-benefit Medicaid beneficiaries who have Medicare entitlement based on ESRD status and then lose full Medicare coverage, please see 87 FR 25107 through 25110 in the proposed rule.

Additionally, we noted that if an individual who had MSP coverage while entitled to Medicare based on ESRD status fails to enroll in the Part B–ID benefit after losing Medicare entitlement based on ESRD status, by the end of the 36th month after the month in which the individual received a kidney transplant, the individual would also lose access to the MSPs after the State provides appropriate notice and fair hearing rights. However, we explained that an individual may re-apply for the MSPs if they later enroll in the Part B–ID benefit under section 402(f) of the CAA. We also noted that

[21] See *https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease* discussing that ESRD prevalence is about 3.7 times greater in African Americans, 1.4 times greater in Native Americans, and 1.5 times greater in Asian Americans.

[22] Gordon, Elisa J., Prohaska, Thomas R., and Sehgal, Ashwin R. *The Financial Impact of Immunosuppressant Expenses on New Kidney Transplant Recipients Clin Transplant* 2008: 22, 736. Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2592494/.*

if an individual did not previously enroll in an MSP while entitled to Medicare based on ESRD status, once they enroll in the Part B–ID benefit they may apply for and enroll in an MSP provided they meet the applicable eligibility criteria.

We also noted that States would be required to enroll individuals in an MSP if they are enrolled in the Part B–ID benefit, apply for an MSP, and meet the income and resource requirements of an MSP. Finally, we stated that individuals enrolled in the Part B–ID benefit and an MSP would lose coverage under both programs if any of four conditions exist for the individual: (1) enrolls in other health insurance that makes them ineligible for the Part B–ID benefit as described in § 407.55(b); (2) becomes eligible for Medicare Part A on the basis of age, disability or ESRD status; (3) voluntarily terminates coverage; or (4) dies. For a more fulsome discussion of how individuals lose eligibility for MSP Part B–ID, see 87 FR 25109 through 25110 of the proposed rule.

We received a number of comments on our proposals to implement MSP Part B–ID.

Comment: Several commenters offered general support for our proposals to implement MSP Part B–ID. A few commenters thanked us for highlighting the Medicaid redetermination process and the critical role it will play in providing continuity of health coverage, including for children. Another commenter supported our efforts for making the Part B–ID benefit affordable through MSPs to individuals living in Medicaid non-expansion States.

Response: We appreciate the support. As noted in the proposed rule at 87 FR 25125, we anticipate that most individuals who are eligible for MSPs and living in States that have opted to expand Medicaid would qualify for the adult group with full Medicaid benefits, including immunosuppressive drugs, and thus we focused our discussion on the MSP Part B–ID benefit for individuals who are eligible for MSP in non-expansion States. We thank the commenters for supporting our efforts to ensure that individuals are aware both of more comprehensive coverage options and that individuals who are unable to afford the Part B–ID benefit are able to seek assistance with premiums and cost sharing through enrollment in the MSPs.

Comment: In addition to the general comments on conducting education and outreach for the Part B–ID benefit, we describe and respond to in section II.B.5. of this rule, several commenters weighed in on conducting education and outreach specific to how the benefit intersects with Medicaid policy and processes. A commenter noted specific support for training Medicaid staff in addition to SHIPs, advocacy groups, providers and community organizations. Another commenter expressed support for our recommendation that States perform early Medicaid redeterminations for individuals who are partial-benefit dually eligible and losing Medicare entitlement based on ESRD. This commenter went on to suggest that CMS send States data on such individuals in advance of the termination from Medicare to facilitate early Medicaid redeterminations. A commenter suggested we educate transplant recipients and their providers about options for continuing coverage, including both the Medicaid redetermination process and subsidies available in the Marketplace. The commenter also stated that CMS could also do more than ''encourage'' States to inform beneficiaries about Part B–ID, by including it as part of their responsibilities under the Medicaid redetermination process at § 435.916. Another commenter recommended that CMS collaborate with SSA and other stakeholders in the transplant sector to help transplant recipients apply for Part B–ID prior to their loss of Medicare entitlement, thereby protecting their rights during the Medicaid redetermination process and MSP Part B–ID determination.

Response: We appreciate the comments focused on outreach and educational efforts around how Medicaid intersects with Part B–ID. We intend to make educational materials available to Medicaid staff as well as advocacy and provider groups. We plan to send States information on individuals enrolled in MSPs before they lose entitlement to Medicare on the basis of ESRD in order to help States conduct early Medicaid redeterminations. We also plan to mail letters to all individuals losing Medicare on the basis of ESRD that describe their health coverage options and list contacts for assistance and additional information.

Comment: Some commenters shared recommendations on operationalizing the MSP Part B–ID benefit, including the need: to ensure States, CMS and SSA can distinguish the limited Part B–ID benefit from full Part B benefits in the various data sources; for CMS to verify inactive Medicaid status for proper eligibility determinations and claims adjudication; and for CMS to issue guidance as quickly as possible given the tight implementation timeframes with the benefit.

Response: We agree that it is very important to provide States timely operational guidance. We have already provided States preliminary operational guidance in advance of finalizing the rule and will be providing more details in the coming months.

We have also been working with SSA over the past several months in order to ensure a smooth implementation of this benefit from an operational perspective. Among other tasks, we have worked on ways to identify the limited Part B–ID benefit from the full Part B benefits in various data sources and how to distinguish between premium and cost sharing payments for Part A and B benefits and MSP Part B–ID benefits to ensure proper payments.

Comment: A commenter requested a delay in the implementation of the Part B–ID benefit until October 1, 2023 or, in the alternative, a waiver of implementation until October 1, 2023. The commenter described several competing system priority updates in the next calendar year and inability to add any new coverage group and benefit not already in its previously planned system updates until the end of 2023.

Response: The CAA mandates that individuals can start signing up for the benefit on October 1, 2022 and that enrollment will begin on January 1, 2023.

Therefore, we cannot delay the effective date of this benefit. There is also no provision in the CAA statute that would allow us to grant a waiver to a particular State to delay enrollment in the MSP Part B–ID benefit. However, States that are not able to accept new values in existing fields from SSA and CMS by the dates prescribed in statute can work with us to manually enroll and report individuals in the MSP Part B–ID benefit. We are available to provide technical assistance to States with either manual workarounds or interpreting buy-in data.

Comment: A commenter expressed concern about inaccuracies in data exchanges between States and federal agencies regarding individuals' Part B–ID status at the start of the program. This commenter stated that there are currently challenges with the data exchange, especially for individuals in QMB and that adding Part B–ID data, particularly during a timeframe that is likely to overlap with the unwinding of the COVID–19 PHE, would create additional challenges.

Response: We agree that it is important to ensure the accuracy of data exchanges between States and federal agencies for the MSP Part B–ID benefit. As stated above, CMS has been working with SSA over the past several months

to ensure a smooth implementation of this benefit from an operational perspective and has already provided States some preliminary operational guidance. We will continue to make ourselves available to provide technical assistance to States as we move closer to the implementation date.

Comment: A commenter inquired whether State Medicaid programs need to expand coverage for immunosuppressive drugs that may not be on a formulary for individuals with Medicaid who are enrolled in the Part B–ID benefit.

Response: We surmise the commenter is specifically referring to individuals who enroll in MSP Part B–ID as a QMB because States are not responsible for paying for Part B–ID cost sharing for individuals enrolled either as SLMB Part B–ID or QI Part B–ID. The Part B–ID benefit is a continuation of the Part B drug coverage for immunosuppressive drugs, and as such, will work the same way for QMBs as it does currently for Part B immunosuppressive drug benefits. This means that to the extent States do not cover a particular immunosuppressive drug on their formulary that is covered as part of the Part B–ID benefit, the State must cover the benefit and pay the Part B–ID cost sharing after Medicare has paid primary. As a QMB, the individual would also be protected from paying any Medicare cost sharing charges out-of-pocket for Medicare-covered immunosuppressive drugs.

Comment: A commenter inquired when buy-in coverage should end for individuals enrolled in the new MSP Part B–ID eligibility groups who provide notice to SSA that they have other health insurance coverage. In particular, the commenter wanted to know whether State payment of the Part B–ID premiums should stop after a particular period of time or if buy-in should continue as long as CMS continues to bill States for the Part B–ID premiums. The commenter further requested that CMS clarify whether Part B–ID coverage continue to pay primary to other coverage until the Part B–ID benefit is terminated.

Response: Under new § 407.62(a)(1), if an individual notifies SSA they are enrolled in other coverage, their Part B–ID enrollment will end the first day of the month after the notification unless the individual requests and qualifies for a different prospective termination date. As long as an individual who reports other coverage continues to meet the other requirements for MSP Part B–ID, buy-in should continue until the individual is disenrolled from the Part B–ID benefit. For individuals enrolled in MSP Part B–ID, Medicare pays primary for Part B–ID until the individual is disenrolled from the Part B–ID benefit.

Comment: A commenter inquired who is responsible for disenrolling individuals in Part B–ID once they receive other health insurance coverage. In particular, the commenter sought to know if it is the responsibility of SSA or the State Medicaid program to notify SSA of other health insurance coverage.

Response: The CAA provides that individuals enrolled in certain other health coverage are not eligible for Part B–ID. As noted previously, new § 407.57 would require that individuals enrolling in Part B–ID attest that they are not enrolled in certain other health coverage, do not expect to enroll in such coverage, and will notify SSA within 60 days of enrolling in other coverage. As such, the individual has the responsibility to notify SSA of other coverage and SSA receipt of this information will trigger termination of Part B–ID under new § 407.62(a)(1). We encourage States to remind individuals to inform SSA as soon as possible, but no later than 60 days of enrolling in Medicaid.

Comment: A commenter inquired whether dual eligible special needs plans (D–SNPs) will help with the coordination of Part B–ID benefits and help ensure continuity of immunosuppressive drug coverage for D–SNP enrollees.

Response: A D–SNP is a type of Medicare Advantage (MA) plan. Under § 422.52(b)(3) in order to be eligible for a special needs plan, an individual must meet the eligibility criteria for an MA plan, which requires an individual be entitled to Medicare Part A and enrolled in Medicare Part B under § 422.50(a)(1). Because Part B–ID is a limited benefit that is distinct from Part B, an individual enrolled in the Part B–ID benefit would not be entitled to Medicare Part A or enrolled in Medicare Part B and would therefore, be ineligible for all MA plans, including a D–SNP. As such, they would have no role in coordination of benefits for Part B–ID. Moreover, any individual enrolled in a D–SNP would need to disenroll upon loss of Medicare entitlement based on ESRD. Similar to any other circumstance when individuals lose their entitlement to Medicare, we would expect the individual's D–SNP to inform them that they are ineligible for continuing D–SNP enrollment. Finally, individuals enrolled in MA plans are enrolled in Medicare Parts A and B, and are thus ineligible for the Part B–ID benefit. After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposals to implement MSP Part B–ID.

4. Part B–ID Benefit Premiums

The Secretary is required by section 1839 of the Act to announce the Part B monthly actuarial rates for aged and disabled beneficiaries. These amounts, according to actuarial estimates, will equal, respectively, one half of the expected average monthly cost of Part B for each aged enrollee (age 65 or over) and one half of the expected average monthly cost of Part B for each disabled enrollee (under age 65). The standard monthly Part B premium represents roughly 25 percent of estimated program costs for aged enrollees and is calculated to be 50 percent of this aged actuarial rate, plus the $3.00 repayment amount required under current law. (Although the costs to the program per disabled enrollee are different than for the aged, the statute provides that the two groups pay the same premium amount.) Premiums may be further adjusted based on an individual's conditions, such as based on late enrollment or reenrollment (§ 408.22), the income-related monthly adjustment amount (§ 408.28), or for beneficiaries subject to non-standard premiums (§ 408.20).

We proposed to create a new paragraph § 408.20(f) to implement the requirements established under section 1839(j) of the Act and propose to modify other existing requirements for Part B premiums found in 42 CFR part 408 as required by statute for the Part B–ID benefit. Specifically, we proposed the following:

- In § 408.20(f)(1), we proposed that beginning in 2022, as required by new section 1839(j) of the Act, the Secretary would determine and promulgate a monthly premium rate in September of each year for the succeeding calendar year for individuals enrolled only in the Part B–ID benefit. Such premium would be equal to 15 percent of an actuarial rate that represents 100 percent of the estimated average monthly cost of Part B for each aged enrollee (age 65 or over). This amount is then rounded to the nearest $0.10.
- In § 408.20(f)(2)(i), the Part B–ID benefit premium would be subject to adjustments specified in §§ 408.20(e) (Nonstandard premiums for certain cases), 408.27 (Rounding the monthly premium), and 408.28 (Increased premiums due to the income-related monthly adjustment amount (IRMAA)).
- In section § 408.20(f)(2)(ii), we proposed that premiums for the Part B–ID benefit would not be subject to

increased premiums for late enrollment or reenrollment under § 408.22.

• In § 408.20(f)(3), we proposed that that the collection of premiums for the Part B–ID benefit would follow the existing requirements governing the collection of Part B premiums set out in § 408.6 and part 408, subpart C of title 42.

We received a comment on our proposals related to premiums for the Part B–ID benefit. The comment and our response follows:

Comment: A commenter was concerned that the monthly premium for Part B–ID would be higher than the monthly premium for regular Part B.

Response: To clarify, the monthly Part B–ID premium for 2023 will be $97.10. This is lower than the otherwise regular Part B premium. The CAA revised section 1839(j) of the Act to require that the Part B–ID premium should be equal to 15 percent of the monthly actuarial rate, that represents 100 percent of the estimated average cost of Part B for enrollees age 65 and over, for that succeeding calendar year. This amount is then rounded to the nearest $0.10.

5. Conforming Changes

Certain individuals are entitled to hospital insurance coverage under Medicare Part A on the basis of ESRD, as provided under section 226A of the Act. Section 406.13(f)(2) currently specifies that the period of entitlement to Medicare Part A for individuals whose Medicare entitlement is based on ESRD ends with the end of the 36th month after the month in which the individual has received a kidney transplant. We proposed to revise § 406.13(f)(2) to provide that beginning January 1, 2023, individuals no longer entitled to Part A benefits due to their coverage ending at the end of the 36th month after the month in which the individual received a kidney transplant, may be eligible to enroll in Part B solely for purposes of coverage of immunosuppressive drugs as described in § 407.55.

Medicare Part B covers health services including prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which Medicare payment is made. Section 410.30(b) currently lays out the requirements governing eligibility for coverage of prescription drugs used in immunosuppressive therapy, stating that coverage is only available for prescription drugs used in immunosuppressive therapy, furnished to an individual who received an organ or tissue transplant for which Medicare payment is made, and provided the individual is eligible to receive Medicare Part B benefits. Chapter 15 of the Medicare Prescription Drug Benefit Policy Manual, section 50.5.1,[23] lists some of the FDA-approved, specifically labeled immunosuppressive drugs. They are: Sandimmune (cyclosporine), Imuran (azathioprine), Atgam (antithymocyte globulin), Orthoclone OKT3 (Muromonab-CD3), Prograf (tacrolimus), Celicept (mycophenolate mefetil, Daclizumab (Zenapax); Cyclophosphamide (Cytoxan); Prednisone; and Prednosolone. However, this is not intended to be an all-inclusive list and is subject to change. The manual guidance states that CMS ''*expects contractors to keep informed of FDA additions to the list of the immunosuppressive drugs.*'' This expectation would carry over to the Part B–ID benefit. MACs have issued articles on this topic and, generally speaking, covered immunosuppressive drugs are oral tablets or capsules. However, certain immunosuppressive drugs may be intravenously infused or intramuscularly injected. The majority of the immunosuppressive drugs have generic equivalents; however, certain newer agents remain available as brand only.

Where the conditions require an infused or injectable immunosuppressive therapy, these would be administered in the physician office or outpatient setting. In this case of the Part B–ID benefit, only the cost of the drug would be covered (not the service of administration). Immunosuppressive therapies covered under Part B are paid based on pricing methodology in 1847A of the SSA (typically, this is an ASP-based payment limit). Payment limits for many immunosuppressive therapies can be found on the ASP Drug Pricing File,[24] which is updated quarterly. Cost sharing is typically 20 percent.

We proposed to revise § 410.30(b) to specify that beginning January 1, 2023, individuals who meet the requirements as specified in section § 407.55 are eligible to receive prescription drugs used in immunosuppressive therapy.

An individual is eligible for enrollment into a Part D plan if certain conditions are met, as set out in section 1860D–1(a) of the Act. Section 423.30(a)(1)(i) of the regulations establishes that an individual is eligible for Part D if they are entitled to Medicare benefits under Part A or are enrolled in Medicare Part B. Section 423.30(a)(1)(i) would be revised to specify that an individual is eligible for Part D if they are entitled to Medicare benefits under Part A or enrolled in Part B, but does not include an individual enrolled solely in Part B for coverage of immunosuppressive drugs under § 407.1(a)(6).

Section 402 of the CAA states that the Secretary may conduct public education activities to raise awareness of the availability of more comprehensive, individual health insurance coverage (as defined in section 2791 of the Public Health Service Act) for individuals eligible under section 1836(b) of the Act to enroll or to be deemed enrolled in the medical insurance program established under this part for purposes of coverage of immunosuppressive drugs.

As a part of implementation, CMS will conduct education and outreach across the broad span of partners (that is, beneficiary advocacy groups, providers, associations, etc.) to ensure awareness and understanding of this benefit. Also, we note that all appropriate beneficiary notices, such as the Medicare based on ESRD pre-termination notice, (discussed in this final rule), the notice that will be provided to individuals who were previously terminated from Medicare based on ESRD to inform of the Part B–ID benefit, as well as the annual notice to individuals that have the Part B–ID benefit, will include information on the availability of, and contact information for, other comprehensive coverage that an individual may want to explore, such as Marketplace or Medicaid coverage. Additionally, as discussed in section II.B.3. of this final rule, we are encouraging States to provide education and assistance to individuals as part of the Medicaid redetermination process. We are also exploring steps to conduct outreach and education for beneficiaries and multiple external partners, including those who regularly assist beneficiaries with health insurance counseling, regarding the most appropriate coverage options for MSP beneficiaries transitioning off Medicare entitlement based on ESRD.

A significant number of the comments we received on the proposed Part B–ID benefit were related to education and outreach efforts needed for successful implementation of the benefit. Those comments and our responses are as follows.

Comment: Several commenters stated that education and outreach efforts were needed to educate beneficiaries, including advocacy groups and SHIPs, as well as States, medical providers, pharmacists, transplant centers, and ESRD Networks on the availability and

[23] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

[24] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.*

scope of this new benefit. A commenter stated that eligibility criteria will not be readily apparent to individuals, and another commenter stated that an effective education and outreach campaign will be critical to ensure individuals do not have gaps in coverage and understand their options for enrollment in the most comprehensive coverage that is available to them. Commenters suggested many forums and methods for messaging, including open forum calls to specifically address technical issues relating to the new Part B–ID benefit. Another commenter suggested that CMS create a detailed booklet (like Medicare & You) as well as a one-pager highlighting the essential details, and requested that CMS create streamlined/simple web-based education specific to the new Part B–ID coverage. A commenter stated that materials should address varying levels of health literacy for this vulnerable community, including pediatric-specific outreach materials.

Several commenters welcomed the opportunity to engage with CMS and other stakeholders on informative notifications and outreach to affected beneficiaries. A commenter suggested that the ESRD Networks be consulted in the development and delivery of culturally and educationally appropriate information.

Response: We thank the commenters for their feedback. We agree that education and outreach efforts should be wide-ranging, timely, and concise, and should be appropriate to inform all impacted stakeholders and beneficiaries. We appreciate the offer to assist us in developing and disseminating information on this important benefit change, and we will take all suggestions under advisement, including recommendations for messaging beneficiaries.

To note, some of our education and outreach efforts will include, but may not be limited to, engaging CMS Regional Offices' Local Engagement & Administration (LEA) teams, communication leads, and CMS clinical arenas—in other words, this will be an all-hands-on-deck initiative. CMS also plans to educate Marketplace Assisters, Navigators, and Agent/Brokers who assist with Marketplace enrollment so they properly understand the Part B–ID benefit as they counsel individuals on more comprehensive coverage options. Coordination with HHS Administration for Community Living (ACL) and their grantees, such as the State Health Insurance Assistance Programs (SHIPs) will also be critical.

Comment: Several commenters supported our proposed processes to notify beneficiaries of the Part B–ID benefit using the pre-termination notice issued by SSA. A commenter stated that information on the Part B–ID benefit, as well as information on other comprehensive coverage options, should be provided earlier in the process to raise awareness and give beneficiaries more time to consider their future coverage options and prepare for their health care needs after their 36-month post-transplant coverage ends. A commenter expressed that specific guidance be provided for those who will lose eligibility for MA coverage because they would no longer be entitled to Part A and enrolled in Part B. Another commenter stated that beneficiaries enrolled in MA Plans should receive the same information in their termination notices as the information made available to beneficiaries who are covered under Medicare Fee-for-Service (FFS).

A couple commenters stated that they shared CMS' concern that individuals might mistake this coverage as equal or similar to comprehensive coverage under other parts of Medicare. They urged CMS to conduct consumer and community testing to evaluate whether such confusion is increased or decreased with different naming conventions and descriptive strategies. Specifically, they suggested testing naming designations that use more plain language and highlight the fact that the coverage is distinct from Part B by putting the modifying word or words before Part B in the name.

Response: Beneficiaries are sent a pre-termination notice by SSA several months before the end of their Medicare entitlement. This pre-termination notice will include notification that the beneficiary's Medicare based on ESRD is ending, other comprehensive coverage options that may be available, and availability of the Part B–ID benefit, including how to apply for the Part B–ID benefit and financial assistance available for the benefit. All beneficiaries whose Medicare based on ESRD is terminating 36 months after a kidney transplant, regardless of whether those beneficiaries are receiving their benefits through Original Medicare (FFS), or through an MA plan, will receive the same pre-termination notice from SSA. We note that individuals who enroll in Part B–ID benefit will be provided with a new Medicare card which will include the specific language that describes the benefit.

We appreciate the support and feedback we have received from the commenters on our proposals related to eligibility, enrollment, effective dates of coverage, termination of, and premiums/cost sharing for the Part B–ID benefit. After review and consideration of all comments, we finalizing all of the Part B–ID benefit regulations as proposed with the exception of the attestation language at § 407.59. We will be finalizing that language to clarify that an individual must attest to SSA in either a verbal attestation, signed paper form provided by SSA, electronic submission, or fax, using procedures determined by SSA.

C. Proposal on Simplifying Regulations Related to Medicare Enrollment Forms (§ 406.7 and 407.11)

We proposed to revise §§ 406.7 and 407.11 to remove references to specific forms that are used to enroll in Medicare Part A and Part B, respectively. This is an administrative change that would simplify existing regulations and would have no impact on current eligibility requirements or enrollment processes or the use or availability of these forms. We proposed to continue to update our forms, including form numbers, and the conditions in which each form is used, through subregulatory guidance because these are procedural, and not substantive rules.

Specifically, we proposed to revise § 406.7 to provide that forms used to apply for Medicare entitlement are available free of charge by mail from CMS or at any Social Security branch or district office or online at the CMS and SSA websites. We also proposed to make technical edits to the text to state that an individual who files an application for monthly Social Security cash benefits as described in § 400.200 to apply also applies for Medicare entitlement if he or she is eligible for hospital insurance at that time. Similarly, we also proposed to revise § 407.11 to provide that forms used to apply for enrollment under the supplementary medical insurance program are available free of charge by mail from CMS, or at any Social Security branch or district office and online at the CMS and SSA websites. Lastly, we also proposed a technical change in the last paragraph of § 406.7 to refer to ''monthly Social Security benefits'' instead of ''monthly social benefits.''

We received some comments on this proposal on Simplifying Regulations Related to Medicare Enrollment Forms. The comments and our responses follow.

Comment: While most commenters were in support of the proposal to remove specific form references from

the regulation to allow future flexibility in updating, creating and removing forms, a commenter was not in support of this proposal because it will confuse beneficiaries and reduce the ability of some to make decisions that benefit them.

Response: Removing the references of specific forms from the regulation text will not confuse beneficiaries nor will it have an adverse effect on a beneficiary's ability to make decisions. As written, the regulation describes the avenues in which a beneficiary can obtain the enrollment forms. Through any of these channels, the beneficiary will be clearly informed of which forms they need to make an enrollment. The forms are not changing as a result of our proposal, nor is the way the forms can be obtained. Removing the form references from regulation will allow CMS to make quick changes to the forms, as needed, which will in turn assist beneficiaries in having clear forms that present the information needed to make an informed enrollment decision.

Comment: A few commenters provided recommendations related to Medicare enrollment forms, while still supporting the changes as proposed. A commenter recommended that CMS use the Health Plan Management System (HPMS) system to notify MA plans about any changes made to Part A and B enrollment forms, in addition to the Paperwork Reduction Act (PRA) information collection comment process. Another commenter recommended that CMS and SSA take this opportunity to create new forms that are easier to understand and to routinely make the forms available in multiple non-English languages and accessible formats.

Response: As noted above, this would be an administrative change that would not affect the use and availability of enrollment forms, nor would it specifically result in the creation of new forms. If, in the future, forms are revised or created, they would have to go through the PRA approval process. In addition, as there are no operational changes resulting from this change, and a separate notification is not needed via HPMS.

We thank the commenters for their feedback on this proposal. After consideration of the comments, we are moving forward with finalizing this proposal and removing the specific form references from regulation. This will allow us the opportunity to explore the suggested form updates provided here, as well as other suggested updates such as alternate formats and multiple languages in the future, in order to make impactful changes that will improve the beneficiary experience.

D. Modernizing State Payment of Medicare Premiums (§§ 400.200, 406.21, 406.26, 407.40 Through 407.48, 431.625, 435.4, 435.123 Through 126)

CMS seeks to modernize the Medicare Savings Programs (MSPs) through which States cover Medicare premiums and cost sharing. As part of these efforts, we proposed updating the various federal regulations that affect a State's payment of Medicare Part A and B premiums (also known as State buy-in) for beneficiaries enrolled in the MSPs and other Medicaid eligibility groups. The proposed rule included policy proposals based on program experience intended to modernize the State buy-in program and technical updates to reflect statutory changes over the last 3-plus decades. We also proposed to codify in the regulations certain administrative practices that have evolved over the years, clarify minimum requirements for the State payment of Medicare premiums, and present options for States to streamline eligibility and enrollment in the MSPs and other Medicaid eligibility groups.

We proposed two major policy proposals: (1) replace decades-old stand-alone buy-in agreements by specifying that all provisions of the buy-in agreement are now set forth in the State's Medicaid State plan; and (2) limit State liability for retroactive Part B premiums for full-benefit Medicaid beneficiaries under a buy-in agreement to a maximum of 36 months prior to Medicare enrollment determination with a good cause exception. These changes will not limit access to benefits, create new liability, or cause other negative impacts for beneficiaries.

With regard to the technical updates, we proposed updates to (1) § 406.21 (individual enrollment), which was last revised in 1996; (2) §§ 406.26 (enrollment under State buy-in), and 407.40 through 48 (State buy-in agreements), which were last revised in 1991; [25] (3) § 431.625 (coordination of Medicaid with Medicare Part B), which was last revised in 1988; and (4) § 400.200 (general definitions), which was last revised in 1983. These revisions would update the buy-in coverage groups, clarify beneficiary protections related to buy-in coverage groups and clarify populations for whom States can obtain federal financial participation. We also proposed to add new §§ 435.123 through 435.126 and to revise § 435.4 (definitions and use of terms) to codify in CMS Medicaid regulations all MSPs under section 1902(a)(10)(E) of the Act.

We noted that these policies would improve the customer service experience of dually eligible beneficiaries as called for under *Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government.* We anticipated our proposals would also advance health equity by improving low income individuals' access to continuous, affordable health coverage and use of needed health care consistent with *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.*

We received multiple comments that were not tied to specific regulatory proposals.

Comment: Many commenters expressed general support for updating the various regulations affecting the State payment of Medicare premiums. Some commenters noted that the proposals would provide additional clarity to States. Others noted that our proposals would expand access to the Medicare Savings Programs and improve their functionality.

Response: We thank commenters for their support. The impact of State buy-in is significant for many beneficiaries. State buy-in provides individuals with extra money in their pocket each month (the standard Part B premium is $164.90 per month in 2023) and helps eligible individuals access the Medicare benefits to which they are entitled. We agree that our proposals would clarify requirements for States and promote access to affordable health coverage and essential medical treatment for underserved individuals.

Comment: A commenter requested that CMS require States to accept and process MSP applications submitted by individuals during the first 3 months of their initial enrollment period for premium Part A or Part B (that is, the 3 months prior to the month they first qualify for Medicare), provided the Social Security Administration has already determined them eligible for Medicare. The commenter contended that State practices to deny MSP applications submitted before the

[25] We note that CMS made a minor technical update to § 407.42 to remove the reference to the obsolete regulatory provision, § 435.114 (Individuals Who Would Be Eligible for AFDC Except for Increased OASDI in the Income Under Pub. L. 92–336) in the November 30, 2016 **Federal Register** (81 FR 86382), entitled ''Medicaid and Children's Health Insurance Programs: Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP,'' (hereinafter referred to as the November 2016 final rule).

individual is entitled to Part A or enrolled in Part B often result in an obligation to pay multiple months of premiums before their MSP coverage starts. According to the commenter, these upfront costs can prevent low-income individuals from accessing their Medicare benefits, lead individuals to delay needed health care, and cause genuine financial hardship.

Response: Although we appreciate the commenter's perspectives on this issue, these comments are outside the scope of the proposed rule. As such, we do not address them in this final rule.

1. State Plan Amendment as Agreement Between State and CMS (§ 407.40)

Section 1843 of the Act provides for ''agreements'' between a State Medicaid agency and the Secretary to facilitate the payment of Part B premiums for Medicare-eligible Medicaid beneficiaries (''buy-in agreements''). All States currently have elected to enter into such agreements and process Part B premium payments as provided under section 1843. Under section 1818(g) of the Act, starting January 1, 1990, States could expand their buy-in agreements to enroll Qualified Medicare Beneficiaries (QMBs) in premium Part A, with the State paying the Part A premiums on their behalf. As of the date of this final rule, 36 States and the District of Columbia include the payment of Part A premiums for QMBs in their buy-in agreement (''Part A buy-in States''), but 14 States use the group payer arrangement to pay Part A on behalf of QMBs under § 406.32(g) (''group payer States'').[26]

To execute agreements under section 1843 of the Act, the Secretary and States initially signed free-standing, written agreements that defined the then-scope of a State's buy-in agreement for Part B and bind the States to follow federal regulations and guidance under section 1843 of the Act. However, none of these original signed agreements have been updated for decades. In lieu of amending the decades-old free-standing written agreements, CMS and States have used Medicaid State plans and State plan amendments (SPAs) to document current State buy-in election choices and modifications. However, there are provisions in the free-standing buy-in agreements that are not reflected in these State plan provisions, and these non-current agreements have never officially been superseded. As such, for a complete picture of the full obligations a State has agreed to under section 1843, it is necessary to review both the free-standing agreement and deemed amendments to this agreement done through the SPA process. This is not an efficient or effective way to reflect the State's obligations under its buy-in agreement with CMS.

As described in the April 2022 proposed rule (87 FR 25113 through 25114), we proposed to use our authority under section 1902(a)(4) of the Act to amend the definition of a State buy-in agreement at § 407.40(b) by specifying that State plan provisions addressing what a State has agreed to under sections 1843 and 1818(g) of the Act constitute the State's buy-in agreement for purposes of those sections, including the scope of a State's buy-in practice, and that all aspects of a State's buy-in agreement with the Secretary, including what is set forth in the original buy-in agreements that is not currently in the State plan, should be set forth in the State's Medicaid State plan. We proposed that the State's submission of a SPA addressing what it is agreeing to under sections 1843 or 1818(g) of the Act or both, and CMS's approval, would thus constitute the ''agreement'' between the two parties for purposes of sections 1843 and 1818(g). We noted that this proposal codifies CMS' long-standing practice of effectuating changes in buy-in policy through the Medicaid State plans, rather than through the free-standing written agreements originally executed with each State. As a result, we stated that all free-standing buy-in agreements would be superseded by provisions related to buy-in practices within a State Medicaid plan.

Further, because approved State plan provisions addressing what a State has agreed to under sections 1843 or 1818(g) or both would constitute the buy-in agreement referenced in those sections, and because there are existing mechanisms for both State modification or termination and CMS enforcement of State compliance, we also proposed to delete § 407.45, which currently addresses a decision by a State to terminate its buy-in agreement, and CMS termination of a State's buy-in agreement for a State failure to comply with it.

We received the following comments, and our responses follow.

Comment: Several comments expressed support for our proposal to replace the old stand-alone agreements by specifying that the provisions of a State buy-in agreement shall be set forth in the State Medicaid plan. The Medicaid and CHIP Payment and Access Commission (MACPAC) noted this change codifies existing policies and helps to clarify State buy-in policies going forward. Other commenters indicated the provision would reduce administrative burden and improve efficiency. A commenter pointed out that this change would improve transparency, as SPAs are typically posted online while the stand-alone buy-in agreements are not.

Response: We thank the commenters for their support and agree that retiring the stand-alone agreements and housing the state buy-in agreement in the State Medicaid plan would promote greater efficiency, clarity, transparency and accountability.

Comment: A commenter contended that there is no place in the current State Medicaid plan that includes the State's buy-in agreement or that reflects the State's buy-in elections and requested that CMS specify whether we will issue a separate template in the State plan to describe State buy-in choices. Other commenters encouraged CMS to work actively with States to update their State plans, and proactively coordinate with all States that utilize a stand-alone agreement to prevent disruption to beneficiaries.

Response: We thank the commenters for their perspectives and agree with the importance of avoiding ambiguity about the prevailing State buy-in elections in each state and preventing disruptions in buy-in coverage for individuals. We do not agree that the State Medicaid plan lacks provisions related to State buy-in practices. As noted in the proposed rule (87 FR 25112), Section 3.2 ''Coordination of Medicaid with Medicare and Other Insurance'' of the State Plan currently includes the State's selection for buy-in. Nonetheless, we anticipate revising the Medicaid State plan template material for States to make buy-in group elections, consistent with this final rule. We also plan to provide technical assistance to States on updating their State plans and retiring stand-alone buy-in agreements, as needed, with the goal of avoiding disruptions to State buy-in. Because the provisions related to State buy-in practices in the State Medicaid plan will supersede the free-standing buy-in agreements, the State Medicaid plan will bind States to follow regulations and guidance under sections 1843 and 1818(g) of the Act.

We did not receive comments on our proposed deletion of § 407.45.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed amendments

[26] The group payer arrangement allows certain parties (for example, States) to pay Part A premiums for a class of beneficiaries. See Program Operations Manual System (POMS) HI 01001.230 Group Collection-General at *http://policynet.ba.ssa.gov/poms.nsf/lnx/0601001230.*

to § 407.40 and § 407.45 specifying that State plan provisions addressing what a State has agreed to under sections 1843 and 1818(g) constitute the State's buy-in agreement.

2. Limiting State Liability for Retroactive Changes and Related Updates (§ 407.47)

Under section 1843 of the Act, States must pay Part B premiums for any individual starting the first month they are both a member of the State buy-in coverage group specified in the buy-in agreement and eligible for Part B. In some instances, SSA determines Medicaid beneficiaries eligible for Medicare for a retroactive period. This generally occurs when an individual under age 65 who files a claim for disability benefits at SSA [27] receives a favorable Social Security Disability Insurance (SSDI) award multiple years after the initial application, and SSA determines the individual eligible for SSDI benefits at or up to 12 months prior to the point of application, even though they were not able to receive SSDI payments timely because eligibility had not yet been determined. Individuals entitled to SSDI become entitled to premium-free Medicare Part A after 24 months of entitlement to SSDI, but in certain cases, an individual's favorable determination of SSDI is retroactive more than 24 months. In that case the determination of SSDI eligibility for a retroactive period for the individual means that the individual's premium-free Part A entitlement is retroactive as well. The individual is also retroactively eligible to enroll in Part B over this period.[28]

As described in the April 2022 proposed rule (87 FR 25113 through 25114), retroactive Medicare Part A entitlement for a Medicaid-eligible individual can have multiple implications for State Medicaid agencies. First, States may, under their buy-in agreement, be liable for Medicare Part B premiums for the retroactive period. If a State learns that SSA established retroactive premium-free Medicare Part A entitlement for a member of a buy-in coverage group, the State must review the individual's eligibility for Part B buy-in over the retroactive period. Under section 1843(d)(2) of the Act and the current version of § 407.47(a), States must pay Medicare Part B premiums for individuals beginning the first month a Medicaid beneficiary is enrolled in Medicaid and qualifies for Medicare, with no limit on retroactivity. Second, when Medicare enrollment is established retroactively for Medicaid beneficiaries, the State must determine if it has already paid a Medicaid claim for the individual, because Medicare is the primary payer for dually eligible beneficiaries when services are covered by both programs. In this situation, under section 1902(a)(25)(B) of the Act and § 433.139(d), the State must seek to recoup Medicaid payments to providers for any Medicare-covered services during the period of retroactive Medicare coverage, unless the State determines it is not cost-effective to do so. If Medicaid recoups funds paid to a provider, the provider may bill Medicare, which may require the provider to obtain an exception to Medicare's 1-year timely filing requirement as described in CMS guidance published in Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 70.7.3. However, the greater the length of time from the date of service, the more labor-intensive and administratively burdensome it is for the State to recoup Medicaid payments from providers, for the provider to submit a claim to Medicare, and for Medicare to process it.

As discussed in the proposed rule (87 FR 25114 through 25115), under section 1843(d)(2) of the Act and the current version of § 407.47(g), States technically became liable for retroactive Part B premiums for such beneficiaries going many years back, starting the first month SSA retroactively established Part A entitlement, with no limit on this retroactivity.[29] However, in implementing a court ruling in *NY State* v. *Sebelius* (N.D. NY, June 22, 2009), CMS adopted a policy under which it does not impose an obligation on States to make retroactive Part B premium payments when SSA operational and systems errors cause lengthy delays in SSDI awards and Medicare eligibility determinations for full-benefit Medicaid beneficiaries and the State cannot obtain the benefit of the Medicare coverage associated with the Part B premium payments the State would otherwise be obligated to make. In addition, CMS currently allows States to request relief on a case-by-case basis from retroactive premiums for periods involving lengthy delays in Medicare determinations to the extent that such delays cover periods for which the State asserts it is too late to benefit from Medicare coverage. CMS considers the potential for beneficiary harm (liability for uncovered medical costs) and the State's recoupment policy (that is, time limits on State actions to recoup Medicaid payments from providers) as factors in assessing these State requests. Similar to the current policy, the proposed rule also ensures that beneficiaries are protected from uncovered medical costs by limiting the application to full-benefit Medicaid beneficiaries and granting a good cause exception if the beneficiary will be harmed, as discussed in 87 FR 25115.

In the proposed rule (87 FR 25114 through 25115), we noted that rulemaking is warranted to ensure that the regulations reflect a clear and consistent policy, transparent to all States, on how CMS is addressing the equitable concerns addressed in the previously discussed court decision and subsequent CMS policy implementing it. Therefore, we proposed to add a new paragraph (f)(1) at § 407.47 under which State liability for retroactive Medicare Part B premiums for full-benefit [30] Medicaid beneficiaries under a buy-in agreement would be limited to a period no greater than 36 months prior to the date of the Medicare enrollment determination. We noted that this proposed revision conceptually aligns with the 2009 court decision limiting State liability for retroactive Medicare Part B premiums for full-benefit Medicaid beneficiaries.

Based on the most recent CMS data, we estimate that out of an average of nearly 150,000 individuals who are newly enrolled in Part B buy-in each month, fewer than 750 Medicaid beneficiaries, or 0.5 percent, require retroactive Part B buy-in for more than 36 months. (In a typical month, approximately 2,250 Medicaid

[27] When individuals file for disability benefits, SSA determines eligibility for both SSDI and supplemental security income (SSI). The same disability requirements apply to both programs, but other requirements differ. As a result, some individuals receive an SSI award while their SSDI claim or appeal is pending.

[28] SSA does not enroll the individual in Part B for the past months unless the individual pays SSA a lump sum amount reflecting the total costs of Part B premiums the individual would have paid had they been enrolled in Part B during that time or the individual is a member of the State buy-in coverage group.

[29] In States with 1634 agreements (''1634 States''), SSA automatically qualifies individuals entitled to SSI for Medicaid and, once they qualify for Medicare, CMS automatically enrolls those individuals in Part B buy-in. In such States, the retroactive disability and Medicare determinations for the SDW individuals resulted in CMS billing for retroactive Part B premiums going back several years. States without 1634 agreements also owed Part B premiums for the individuals enrolled in SSI and Medicaid during past period, but CMS only billed the state after the State requested buy-in for these individuals.

[30] ''Full-benefit'' Medicaid coverage, in the context of individuals who are considered dually eligible, generally refers to the package of services, beyond coverage for Medicare premiums and cost sharing, that certain individuals are entitled to under § 440.210 and § 440.330.

beneficiaries are retroactively enrolled in Part B buy-in for 12 months or more.)

In the proposed rule (87 FR 25115), we anticipated that our proposal would reduce administrative burden on providers for beneficiaries with Medicare determinations more than 36 months in the past, by relieving providers of Medicaid recoupment activities States may find cost-effective to pursue and the need, therefore, to resubmit the claim to Medicare. Additionally, we noted that it would not create beneficiary liability since Medicaid would have covered any medical costs the beneficiary incurred, and absent State buy-in, the individual would not be enrolled in Part B and, therefore, would not owe any premiums for periods greater than 36 months in the past.

Because this proposal reduces burden and promotes efficiencies, clarity and predictability for providers, States, and CMS, we found it consistent with the authority under section 1902(a)(4) of the Act for the Secretary to find methods of administration ''necessary for proper and efficient administration'' of the Medicaid program.

Although we considered proposing limits on State premium liability for time periods longer or shorter than 36 months, including a range from 24 to 60 months, we proposed a 36-month limit for two primary reasons. First, we stated our belief that Medicaid Management Information Systems (MMIS) would still have Medicaid claims data for dates of service going back at least 36 months. Second, we maintained that the length of time in our proposal is consistent with section 1902(a)(25)(I)(iv) of the Act, under which States must require health insurers, including Parts C and D plans, to accept claims submitted by the State within a minimum of 3 years from the date of service.

As discussed in the proposed rule (87 FR 25115), our proposal to limit State liability for retroactive Part B premiums applies only when Medicaid beneficiaries receive retroactive SSDI and Medicare eligibility determinations from SSA, not when Medicare entitlement delays stem solely from federal buy-in system errors or delays. Under section 1837(h) of the Act, the Secretary has discretion to grant relief to correct or eliminate the effects of such errors or inaction. Our proposal also does not address enrollment delays which can affect all members of a State buy-in coverage group, including individuals enrolled in partial-benefit Medicaid. The existing process for these cases allows the Secretary to consider the conditions of each case, and avoid harm to the beneficiaries.

We requested comment on our proposed 36-month limit, including how it compares with State Medicaid recoupment time-limits, or on alternative options to balance accuracy and burden. We also proposed a ''good cause'' exception to the 36-month limit in proposed paragraph (f)(2). This proposed provision would allow an exception for retroactive periods of more or less than 36 months if a currently unforeseen situation arises in which application of the proposed paragraph (f)(1) would result in harm to a beneficiary. In evaluating the good cause exception, the primary consideration would be whether the beneficiary has unpaid medical bills and needs Medicare coverage during the retroactive period for unpaid medical bills. We noted that new paragraph (f)(2) would also allow CMS to provide relief to States for periods of less than 36 months if we determine the State could not benefit from Medicare and limiting State liability would not result in harm to the beneficiary.

We received the following comments, and our responses follow.

Comment: Many commenters expressed general support for our proposal to limit State buy-in liability for the retroactive periods greater than 36 months. A commenter noted that it would reduce administrative burdens for States and providers without negatively impacting access to care for beneficiaries. MACPAC stated that the 36-month limit is in line with previous MACPAC recommendations for Medicaid program integrity efforts to make efficient use of federal resources and to minimize undue burden on States or providers. Some commenters supported the 36-month limit on retroactive liability in light of its inclusion of a ''good cause'' exception to allow for retroactive periods of more or less than 36 months. A commenter explained that an exception to cover a period exceeding 36 months may be needed on the rare instance that a beneficiary receives care from a non-Medicaid provider who accepts Medicare during an earlier period and needs Medicare coverage to address an outstanding medical debt incurred. Another commenter supported the ability for States to request relief for periods of less than 36 months if CMS determines the State cannot benefit from Medicare and limiting State liability would not result in harm to the beneficiary.

Response: We appreciate the widespread support for our proposal. The comments bolster our belief that this change would reduce unnecessary burden on providers and help State Medicaid programs run more efficiently without negative impact for beneficiaries. We agree with the need for the good cause exception to address rare cases in which a Medicaid beneficiary needs Medicare coverage to pay for care that Medicaid does not cover during a period further than 36 months in the past. We also concur that the 36-month limit strikes the right balance between payment accuracy and efficiency while the good cause exception provides CMS the flexibility to provide relief to States for periods of less than 36 months if we find that Medicare was unavailable during that time and the beneficiary would not be harmed.

Comment: A commenter asserted that the holding of the court in *NY State* v. *Sebelius* resulted in a 24-month retroactive buy-in limit in a particular State and questioned whether our proposal in the proposed rule would change the State's current 24-month limit. The commenter also questioned whether under our proposal, a State Medicaid program is only required to pay the premium for the retroactive period if there is a benefit to both the State and the beneficiary, and not necessarily back to when the beneficiary is entitled to Part A.

Response: We thank the commenter for the feedback, but we do not agree that the federal court ruling required a blanket 24-month retroactive limit in any particular State. In our implementation of the court's ruling, CMS began granting States' requests for relief, on a case-by-case basis, from retroactive premiums that cover periods for which the State contends it is too late to benefit from Medicare coverage. In assessing these State requests, CMS has considered the potential for beneficiary harm and the State's recoupment policy. We clarify, that under the good cause exception in new § 407.47(f)(2), we would grant a request for a retroactive limit of 24 months if we conclude that Medicare is unavailable beyond that period (for example, the State has a recoupment policy of 24 months) and the beneficiary would not be harmed. Absent approval of a good cause exception, the 36-limit would apply in all States.

Comment: Some commenters expressed support for this policy, but requested clarification on CMS' intention to reject buy-in records from beyond 36 months in the past. A few commenters noted the likely need for States to alter their own buy-in systems to refrain from submitting records from periods prior to 36 months.

Response: We appreciate the commenters' request for clarification on

the State and system changes required for this provision. We are still exploring these questions and the best ways to operationalize our proposal. Therefore, we are modifying the provision's effective date to January 1, 2024. This modification will provide additional time for CMS to explore and account for any State impacts and afford States a more reasonable timeline to implement systems changes should they prove necessary amidst competing systems priorities (for example, related to Part B–ID implementation and the unwinding of the COVID–19 PHE). This delay will not harm States and beneficiaries since CMS has an existing process to grant State requests for relief on a case-by-case basis when a beneficiary would not be harmed.

Comment: A few commenters pointed out situations in which a State may still have retroactive State buy-in liability for a period beyond 36 months. A commenter stated that retroactive limits should not apply to cases of Medicaid beneficiaries who were enrolled in Medicare but were improperly excluded from buy-in and need retroactive buy-in to rectify the missing period. Another commenter noted States may be required to pay retroactive premiums for periods greater than 36 months in situations in which an individual loses Medicaid coverage, later enrolls in Medicare, and subsequently regains Medicaid eligibility with a retroactive start date that overlaps with the previous Medicaid termination date. The commenter stated that the new proposed SEP following the loss of Medicaid coverage described in section A.2.D of the April 2022 proposed rule could increase the incidence of these cases.

Response: The first example above appears to describe a situation in which a clerical or other error prevented an individual from being enrolled in buy-in for the entire period the individual was eligible for buy-in. We agree that in this situation, the State would need to buy-in for the missing period of coverage to correct the buy-in coverage period. As such, this situation would be outside our proposed provision limiting retroactive Part B premium liability for periods exceeding 36 months. Similarly, we concur that our proposal does not limit buy-in liability in the second example described above, as the second example seems to describe past buy-in liability for individuals who are retroactively re-enrolled in Medicaid after they enrolled in Medicare whereas our proposal involves individuals who are still eligible for Medicaid when they become retroactively entitled to Medicare. Our proposal does not address this situation, but we will consider future rulemaking to limit State liability for retroactive periods in other situations based on program experience.

Comment: A commenter requested clarification on whether the new retroactivity limit in § 407.47(f) would supersede existing provisions in § 407.47(c), which requires States to pay Medicare premiums for individuals the first month they are a member of the buy-in coverage group and eligible for Part B.

Response: We thank the commenter for their question. We clarify that the retroactivity provisions in paragraph (f) are exceptions to the general rules laid out in paragraphs (b), (c), and (d). To alleviate confusion, we are revising our proposed regulatory text in this regard. We are also correcting obsolete cross-references to § 407.42 in those three paragraphs to align with our proposed amendments to that section described in section II.D.3.e. of this final rule.

In our proposed rule (87 FR 25115), we further proposed modifying § 407.47(a) to clarify our current requirement that States consider all bases of membership in the buy-in coverage group to determine the start date of buy-in. Under section 1843(d)(2) of the Act and § 407.47(a), the beginning of an individual's buy-in coverage period depends on the type of medical assistance they receive under the Medicaid State plan. Many individuals who qualify as a QMB or a SLMB also qualify under separate Medicaid eligibility groups. If a State determines that an individual is eligible for the QMB eligibility group and a separate Medicaid eligibility group, the individual may first become designated as a member of the buy-in coverage group corresponding to the non-QMB Medicaid eligibility group under which the individual is determined eligible, based on the effective date of such eligibility before they qualify for the buy-in coverage group corresponding to the QMB eligibility group. To determine the start date of the buy-in coverage period, our proposal clarifies at paragraph (a)(2) that the State must consider the earlier of the buy-in effective dates for the applicable group.

As discussed in the proposed rule (87 FR 25115 through 25116), we anticipated that our proposal on the effective date of buy-in coverage for individuals who qualify for the buy-in coverage group upon multiple bases would provide greater transparency and certainty to States and beneficiaries, and address confusion about existing requirements. We did not receive comments on our proposed clarification of current requirements under § 407.47(a).

In the proposed rule (87 FR 25122), we discussed our consideration of revisions to § 406.26 and § 407.40 to remove premium liability for States in other situations in which Medicare benefits are not available. The 2009 decision in *NY* v. *Sebelius* enjoined CMS from billing New York during periods of retroactive Medicare eligibility in which the State would not benefit from Medicare (that is, it was too late for Medicare benefits to be provided). We cited our belief that there may be similar situations in which Medicare eligibility can be established but Medicare benefits would not be provided. For example, individuals who are incarcerated or residing overseas may still retain entitlement to Medicare but be ineligible for payment for services because of their status.

We requested comment on the implications of limiting liability for States because Medicare is unavailable in these two examples or any others.

We received the following comments, and our responses follow.

Comment: Several commenters expressed support for removing Medicare payment responsibility from State Medicaid programs for individuals who are incarcerated as defined under the Medicare regulations at § 411.4(b). They noted that CMS encourages States to suspend Medicaid coverage during incarceration to facilitate the timely restart of Medicaid coverage upon release, easing burdens on both the State and the individual. However, these commenters contended that because States must still pay Medicare premiums for individuals with suspended Medicaid status, States have financial incentives to terminate rather than suspend Medicaid for dually eligible individuals who are incarcerated. A commenter also pointed out that limiting State premium liability for dually eligible beneficiaries, including those with suspended Medicaid status, comports with a federal interagency commitment to reduce barriers to reentry and ensure than individuals returning to the community do not experience gaps in health coverage.

Response: We thank the commenters for their perspectives. We agree with the need to remove disincentives to Medicaid suspension policies, which improve administrative efficiency and mitigate coverage gaps for individuals exiting the penal system. However, we do not include a provision to limit premium liability during incarceration in this final rule given the complicated operational, legal, and systems issues

involved and the need to obtain input from stakeholders on these matters, including through notice and comment rulemaking. However, we will consider these comments in the development of future rulemaking.

Comment: A commenter expressed concern with removing State liability for Medicare premiums while individuals are incarcerated, noting that Medicare may currently pay for services provided to inmates in cases where State or local law requires those individuals or groups of individuals to repay the cost of medical services they receive while in custody under § 411.4(b). The commenter contended that removing State liability for buy-in during periods of incarceration in States that require individuals to repay the cost of medical after release would impose significant financial burden on individuals post-release and requested that CMS create an exception for these instances.

Response: We thank the commenter for raising the possible negative consequences of limiting buy-in liability during incarceration due to this exception to the Medicare exclusion of payment under § 411.4(b). While we are not finalizing any such proposal at this time, we will consider the commenter's input for future rulemaking.

Comment: A commenter noted their general support for suspending premium liability when Medicare is unavailable because the beneficiary is overseas.

Response: We thank the commenter for their input, but do not include a provision to limit premium liability for overseas individuals in this final rule given the complicated operational, legal, and systems issues involved and the need to obtain input from stakeholders on these matters, including through notice and comment rulemaking.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposal at § 407.47 with two modifications. First, we are making the 36-month limit on State retroactive liability and good cause exception effective January 1, 2024. Second, we are finalizing technical corrections to the regulation text originally proposed to clearly designate the new retroactivity limit in § 407.47(f) as an exception to the general rules described in paragraphs (b), (c), and (d) in that section and to remove outdated cross-references to other sections.

3. Technical Changes to Regulations on State Payment of Medicare Premiums

a. Revisions to General Definitions (§ 400.200)

Section 400.200 includes general definitions applicable to chapter IV of Title 42. In the proposed rule (87 FR 25116), we proposed to amend Medicaid regulations to add a new definition of the Medicare Savings Programs and to codify the Qualified Medicare Beneficiary (QMB), Specified Low Income Beneficiary (SLMB), Qualifying Individuals (QI), and Qualified Disabled Working Individual (QDWI) eligibility groups for the first time since their enactment. As such, we proposed to replace the existing definitions of QMB and QDWI in § 400.200 with streamlined references to the proposed new QMB definition in § 435.123 and the proposed new QDWI definition in § 435.126, respectively. We also proposed to add definitions for the Medicare Savings Programs, SLMB, and QI in § 400.200 that reference the corresponding proposals defining the Medicare Savings Programs in § 435.4 and the proposed codification of SLMB in § 435.124 and QI in § 435.125. We anticipated that the proposals in § 400.200, and related proposals in Part 435, would bring the regulations in conformance with existing statute and policy and promote consistency and clarity for States.

We did not receive comments on our proposed revisions and additions to the definitions in § 400.200.

b. Revisions to Individual Enrollment (§ 406.21)

Paragraph (a) of § 406.21 describes basic limitations on the timing of enrollment in Medicare Part A, in which an individual eligible for Part A may only enroll during his or her IEP, a GEP, an SEP, or, for Health Maintenance Organization/Competitive Medical Plan (HMO/CMP) enrollees, a transfer enrollment period, as set forth in paragraphs (b) through (f). At 87 FR 25116, we proposed to modify paragraph (a) to specify that such Medicare enrollment periods do not apply to individuals enrolling in Part A through a buy-in agreement, as defined in § 407.40. We noted that the provision would codify long-standing policy that QMB-eligible individuals may enroll in Part A at any time of year, without regard to the enrollment periods currently specified in paragraph (a).

We received the following comment, and our response follows.

Comment: A commenter expressed appreciation for this update and the clarity of the proposed revisions, due to confusion at the State level about some of the details in these regulations.

Response: We thank the commenter for their support and anticipate that this provision will enhance clarity and accountability.

c. Revisions to Enrollment Under State Buy-In (§ 406.26)

Section 406.26 describes enrollment in Medicare Part A through the buy-in process. In the proposed rule at 87 FR 25116, we proposed to add a new paragraph (a)(3) to codify long-standing policy against discrimination in the enrollment process, specifying that States with a buy-in agreement in effect must enroll any applicant who meets the eligibility requirements for the QMB eligibility group, with the State paying the premiums on the individual's behalf. We noted that, consistent with current policy, this provision prohibits States from applying a cost-effectiveness test to choose which individuals to enroll in QMB. We also proposed amending paragraph (b)(2) to clarify that, under a buy-in agreement, as defined in § 407.40, QMB-eligible individuals can enroll in premium hospital insurance (that is, premium Part A) at any time of the year, without regard to Medicare enrollment periods. As discussed in the proposed rule at 87 FR 25116, this proposal would codify long-standing policy.

We received the following comment, and our response follows.

Comment: A commenter expressed appreciation for this update, and the clarity of the proposed revisions, due to confusion at the State level about some of the details in these regulations.

Response: We thank the commenter for their support and anticipate that this provision will enhance clarity and accountability.

d. Revisions to Enrollment Under a State Buy-In Agreement (§ 407.40)

In our proposed rule at 87 FR 25116, we included a series of revisions to § 407.40 to reflect statutory updates and codify agency practices related to buy-in agreements.

In § 407.40(a), which describes pertinent legislative history on the State buy-in agreements, we proposed to add new paragraphs (a)(6) through (a)(9) to cover other statutory changes since § 407.40 was last updated in 1991.

In § 407.40(b), which defines terms related to buy-in agreements, we proposed several changes. First, we proposed to replace the term ''section'' with the term ''subpart C'' because terms defined here appear throughout this subpart, not only in § 407.40.

Second, we proposed to revise the definition for aid to families with dependent children (AFDC) because some Medicaid eligibility groups remain tied to AFDC, as that program existed as of July 16, 1996, prior to its elimination.

Third, we proposed to remove the definition of ''Qualified Medicare Beneficiary'' because the term is already defined in § 400.200.

Fourth, we proposed to revise the definition of State buy-in agreement, as discussed in detail in 87 FR 25112 through 25113 of the proposed rule.

Fifth, we proposed to add a definition of a ''1634 State'' to mean a State that has an agreement with SSA, in accordance with section 1634 of the Act, for SSA to determine Medicaid eligibility on behalf of the State for individuals residing in the State whom SSA has determined eligible for SSI.

Sixth, we proposed to add a definition of buy-in coverage group to mean a coverage group described in section 1843 of the Act that is identified by the State and is composed of multiple Medicaid eligibility groups specified in the buy-in agreement.

In § 407.40(c), which describes basic rules for enrollment under buy-in agreements, we proposed to revise paragraph (c)(1) to clarify that States with buy-in agreements in effect must enroll any individual who is eligible to enroll in Part B under § 407.10 and who is a member of the buy-in coverage group, with the State paying the premiums on the individual's behalf. We noted this change aligns with the newly proposed § 406.26(a)(3), which we discussed earlier in this final rule. Additionally, we proposed new text to clarify that States initiate buy-in for eligible individuals who are enrolled in the buy-in coverage group at any time of the year, without regard to Medicare enrollment periods. We explained that if a member of a buy-in coverage group is already enrolled in either Medicare Part A or B, the State will directly enroll the individual in buy-in and refrain from referring the individual to SSA to apply for Medicare.

We also proposed to add a new paragraph, at § 407.40(c)(5), which was incorrectly identified as § 407.40(c)(4) in the NPRM, to reflect that in a 1634 State, CMS will initiate, on behalf of the State, Part B buy-in for individuals receiving SSI. We proposed to codify this policy to clarify that all States must ensure that buy-in is initiated, as this current policy has been inconsistently applied in some States.

Finally, we proposed to add another new paragraph, at § 407.40(c)(6), which was incorrectly identified as § 407.40(c)(5) in the NPRM, to codify a requirement that premiums paid under a buy-in agreement are not subject to increase because of late enrollment or reenrollment.

We received comments on our proposed revisions and additions to enrollment regulations pursuant to a State buy-in agreement in § 407.40.

Comment: Some commenters supported our proposal because it codifies the policy that people with QI, like those with QMB and SLMB, may enroll in Part B under a buy-in agreement outside of Medicare enrollment periods.

Response: We thank the commenters for their support. As stated previously, we anticipate updating these regulations to reflect current policy and statute will enhance clarity and accountability and promote access to buy-in coverage.

e. Revisions to Buy-in Coverage Groups Available for Part B (§ 407.42)

Section 407.42 describes the Part B-related buy-in coverage groups authorized under section 1843(b) through (g) of the Act for the 50 States, the District of Columbia, and the Northern Mariana Islands. It appears that all States except one have elected the option under current paragraph (a) to cover individuals who are deemed recipients of the former AFDC program as cash assistance recipients for buy-in. As described at 87 FR 25117 through 25118 of the proposed rule, although we also consider individuals eligible under section 1931 of the Act to be deemed recipients of the former AFDC program, we have not previously identified such individuals as optional deemed cash recipients for the purposes of buy-in. Therefore, we clarified that individuals eligible under section 1931 of the Act are optional deemed recipients of cash assistance for the purposes of buy-in based on their classification as deemed recipients of AFDC. As such, we proposed allowing States to designate all deemed recipients of AFDC (that is, both children eligible based on title IV–E and individuals covered under section 1931 of the Act) as cash assistance recipients with eligibility groups related to SSI/SSP, or to only cover individuals who receive or are deemed to receive SSI/SSP as cash assistance recipients for buy-in.

As discussed in the proposed rule (87 FR 25117 through 25118), § 407.42 has been a source of confusion for States and other stakeholders. We anticipate that replacing it with a streamlined listing of the buy-in coverage groups, together with their underlying eligibility groups, is more readily understandable for all parties. First, we proposed replacing the existing regulation text in paragraph (a) with a general requirement that States must select one of the buy-in coverage groups listed in paragraph (b). We then proposed modifying the remaining buy-in coverage groups in paragraph (b) together with the eligibility groups they contain.

The modified buy-in coverage groups we proposed in paragraph (b) are as follows:

- Group 1: Individuals who are categorically eligible for Medicaid and:

++ Receive or are deemed to receive SSI or State supplemental payments (SSP), or both; and

++ At State option, individuals described in section 1931 of the Act or children with adoption assistance, foster care, or guardianship care under title IV–E.

- Group 2: All individuals described in Group 1 and three MSP eligibility groups (QMB, SLMB, and QI).
- Group 3: All Medicaid eligibility groups (that is, all individuals eligible for Medicaid).

We received the following comments, and our responses follow.

Comment: A commenter requested an explanation on why CMS is now proposing to require that States include individuals covered under section 1931 of the Act and the Temporary Assistance for Needy Families (TANF) program as deemed cash recipients for the purposes of buy-in. The commenter noted that when the AFDC program was eliminated in 1997, CMS told States that members of the TANF population were not considered cash assistance recipients for the purposes of buy-in. The commenter also questioned if CMS would allow enhanced FMAP for States to change their systems to include this population in buy-in.

Response: We acknowledge the commenter's concerns but clarify that we are not proposing to add, as an independent buy-in coverage group, recipients of the TANF program under § 407.42. As indicated in the proposed rule, TANF eligibility does not serve as a link to Medicaid eligibility, and there is thus no authority for a TANF-based buy-in coverage group under § 407.42.

The proposal to add to § 407.42 individuals eligible for Medicaid on the basis of section 1931(b) of the Act is part of our effort to update the buy-in regulations that, with a minor exception, CMS has not revised since 1992. To reflect the repeal of the AFDC program, we proposed to eliminate AFDC recipients as a buy-in population from § 407.42. However, the *deemed* AFDC population remains in Medicaid

statute and regulations.[31] As we explained in the proposed rule (87 FR 25117), federal law requires that, for purposes of Medicaid eligibility, individuals who are receiving adoption assistance, foster care, or guardianship care under Title IV–E of the Act, or low-income families described in section 1931(b)(1)(A) of the Act, be treated as deemed AFDC recipients. As explained previously, while CMS has previously recognized Title IV–E eligible Medicaid beneficiaries to be deemed AFDC recipients for purposes of the buy-in populations in sub-regulatory guidance, we have not yet confirmed the same for Medicaid beneficiaries eligible under section 1931 of the Act. We therefore proposed to confirm in this revision of § 407.42 that individuals eligible for Medicaid on the basis of their receipt of assistance under Title IV–E of the Act, or being described in section 1931 of the Act, are deemed cash assistance recipients for the purposes of buy-in.

To the extent that additional systems changes are needed, States may seek an enhanced matching rate as described in 45 CFR part 95 subpart F and Part 433 subpart C. States may submit an advanced planning document requesting approval for a 90/10 enhanced match for the design, development and implementation of their Medicaid Enterprise Systems initiatives that contribute to the economic and efficient operation of the program, including technology supporting implementation of additional Medicaid eligibility groups and related maintenance and operations.

Comment: A commenter requested that CMS clarify whether the State option under Group 1 for deemed AFDC recipients is a single option that includes all deemed AFDC recipients or whether States may select certain deemed AFDC recipients for buy-in.

Response: We thank the commenter and clarify that the State option under Group 1 for deemed AFDC recipients is a single option. Individuals eligible for Medicaid either on the basis of section 1931(b) of the Act or their receipt of adoption assistance, foster care, or guardianship care under title IV–E of the Act are examples of individuals who would necessarily be included in a State's election of this option.

Group 1 necessarily includes subgroups (b)(1)(i) (relating to Medicaid-eligible SSI and SSP recipients) and (b)(1)(ii) (relating to Medicaid-eligible deemed SSI and SSP recipients). At State option, Group 1 may also include subgroup (b)(1)(iii) (relating to Medicaid-eligible deemed AFDC recipients). To address any misunderstandings, we are modifying the regulation text to clarify that Medicaid-eligible deemed AFDC recipients, if included by the State, must encompass individuals eligible for Medicaid on the basis of section 1931(b) of the Act as well as individuals eligible for Medicaid based on their receipt of adoption assistance, foster care or guardianship care under part E of title IV of the Act.

Comment: A commenter questioned why the MSPs are considered a State option for buy-in when the MSPs are all mandatory coverage groups.

Response: We thank the commenter for the opportunity to clarify this provision. While the MSP eligibility groups (QMB, SLMB, and QI) are mandatory eligibility groups in the Medicaid program, section 1843 of the Act makes it an option for States to include them in their buy-in coverage groups for Part B. However, as noted previously, all States have elected to provide buy-in coverage for the MSPs under their State buy-in agreements. States cannot pay the Part B premiums on behalf of individuals who receive social security retirement or disability payments unless the individual is covered by the buy-in agreement.

Individuals whom a State enrolls under its buy-in agreements with CMS are exempt from the general rules governing Medicare enrollment periods, premium penalties and mandatory withholding of Title II benefits pursuant to sections 1840 and 1843 of the Act. Therefore, although the MSP groups are optional eligibility groups for buy-in agreements under section 1843, the MSPs function as mandatory groups for buy-in.

Comment: A commenter recommended that medically needy groups be excluded from Group 3 because medically needy individuals may wish or need to use Medicare premium payments to meet their spenddown amount, helping to ensure their Medicaid eligibility in a given budget period. The commenter further noted that including medically needy individuals for State buy-in causes individuals to cycle on and off of State buy-in depending upon whether the individual has met their spenddown amount in a given budget period, resulting in inconsistent and potentially harmful consequences for such individuals. The commenter also requested that CMS revise the buy-in coverage groups under § 407.42 to allow States to include in their buy-in data exchange with CMS individuals for whom the State pays Medicare premiums with State-only funds.

Response: We share the commenter's concern about the potential loss of Medicaid eligibility and buy-in coverage for medically needy individuals. However, the statutory authority for States to expand their buy-in populations beyond cash program and deemed cash program recipients is described in section 1843(h)(1) of the Act. This provision offers States a choice of additional buy-in populations including (A) individuals who are eligible to receive medical assistance under the plan of such State approved under title XIX, or (B) Qualified Medicare Beneficiaries (as defined in section 1905(p)(1) of the Act). CMS interprets section 1843(h)(1) of the Act to mean that, if a State does not elect to add all eligibility groups covered under its State plan to its buy-in agreement, beyond cash assistance and deemed cash program recipients, the QMB group is the only State-plan eligibility group which a State may selectively add to its buy-in agreement. (As described in the proposed rule (87 FR 25118), we proposed to update § 407.42 to clarify that the reference to QMB includes QMB, SLMB, and QI because 1843(h)(3) of the Act specifies that the reference to QMB includes SLMB and the State plan pages for buy-in treat QI like QMB and SLMB, linking the three eligibility groups under one buy-in coverage group.) CMS does not interpret section 1843(h)(1) to permit a State to selectively choose other eligibility groups for its buy-in agreement, such as all categorically needy groups (which would have the effect of excluding medically needy individuals). Therefore, we decline to accept the commenter's recommendation to allow States to cover the Part B premiums under their State buy-in agreement for all Medicaid eligibility groups except the medically needy.

Further, as discussed previously, States can only pay the Part B premiums on behalf of individuals who are members of the State's buy-in coverage group and eligible for Part B. We clarify that the State buy-in data exchange with CMS is used to pay Part B premiums for individuals covered under the State buy-in agreement, regardless of whether States receive FFP for their coverage of Part B premiums under § 431.625. Accordingly, we do not agree that further revisions to § 407.42 are warranted. However, we are available to provide technical assistance to States regarding the appropriate use of the State buy-in data exchange with CMS.

[31] Notwithstanding the repeal of the AFDC program, section 1902(a)(10)(A)(i) of the Act, which describes the mandatory Medicaid eligibility groups, retains the reference in subparagraph (I) to AFDC recipients.

The proposed rule reflected the three buy-in coverage groups that remain after updating and simplifying the eligibility groups. We also solicited comments on two sets of alternatives. The first alternative would have further reduced the number of Part B buy-in coverage groups under § 407.42 from our proposed three groups to two groups (that is, by narrowing the buy-in coverage group options to groups 2 and 3). The second alternative would have required all States to include all deemed AFDC eligibility groups as deemed recipients of cash assistance. We received no comments on either of these alternatives. However, we may consider this issue for future rulemaking.

f. Buy-In Programs in the U.S. Territories (§ 407.43)

We also solicited comments on updating § 407.43, which governs buy-in coverage groups for the four U.S. territories of Puerto Rico, American Samoa, U.S. Virgin Islands, and Guam,[32] similar to our proposal to streamline and clarify buy-in coverage groups in § 407.42. We did not propose revisions to § 407.43 in the proposed rule for the reasons described at 87 FR 25122 and instead sought comment on whether updating the buy-in coverage groups in § 407.43 with a more succinct framework would aid Medicaid agencies in the U.S. territories in administering their buy-in programs and improve beneficiary experiences.

We did not receive comments on this issue.

g. Revisions to Termination of Coverage Under a State Buy-In Agreement (§ 407.48)

Section 407.48 describes the process for terminating an individual's coverage under a State buy-in agreement when they are determined ineligible by either CMS or the State.

As discussed in the proposed rule at 87 FR 25118, States must communicate all disenrollment information through an established data exchange process with CMS. To align the regulation with current agency practice, we proposed amending paragraphs (c)(1) and (c)(2) and adding a proposed new paragraph (e) that would require CMS to prospectively convey to States, on a quarterly basis, a schedule of processing cut-off dates for each calendar month.

Delays in the receipt of buy-in terminations by CMS impact State and beneficiary liability after individuals lose eligibility for Medicaid and the State buy-in coverage group.[33] As currently described in paragraph (c)(1), CMS must receive a State buy-in termination notice during the second month after the individual loses eligibility in order for CMS to stop charging the State for Part B premiums the first month the individual no longer qualifies.

However, as described in the proposed rule (87 FR 25119), if delays in data exchange cause the State to send the termination notification for an individual with an effective date that is earlier than the second month before the processing month, under paragraph (c)(2), CMS will adjust the buy-in termination to the second month prior to the month CMS receives the deletion request. The State remains liable for premiums through the earlier months.

We did not receive comments on our proposed revisions to termination of coverage provisions in § 407.48.

We considered an alternative proposal for future rulemaking addressing beneficiary payment requirements after termination. Currently, when federal systems eventually process the buy-in termination, SSA can retroactively recoup up to 2 months of premiums from the individual's Social Security check. In practice, after buy-in termination, SSA deducts 3 months at a time to account for 2 months' retroactive premiums plus the current processing month.[34] We noted that when SSA deducts 3 months of premiums, this can jeopardize the individual's ability to pay for food and rent in the first month, increasing the risks of hunger or eviction.

We considered proposing further modifications to § 407.48(c) to limit the number of month of premiums for which SSA may immediately bill beneficiaries when buy-in ends. However, we did not formally propose a change, and instead solicited comments to inform future rulemaking on this topic.

We received the following comments, and our responses follow.

Comment: Several commenters expressed support for changing these policies because deducting multiple months of premiums from a single Social Security check can cause serious hardship to low-income individuals, as they rely on that source of income to assist with paying for food, rent, and other life's necessities. Some commenters recommended that the repayment of back premiums be spread over 6 to 12 months to minimize any negative impact on individuals, some of whom lose Medicaid eligibility for procedural reasons and remain income-eligible for Medicaid. A commenter urged at a minimum that those facing recoupment of back premiums be placed on a payment plan of $10 per month for the 2-month liability, which is the same payment schedule that Part D Low-Income Subsidy beneficiaries can request with respect to Social Security overpayments under Social Security Administration program instructions. The commenter also requested that the payment plan be automatic in light of program experience showing that low-income beneficiaries have difficulty understanding correspondence about their benefits and frequently do not understand changes until a negative event takes place. The commenter added that many individuals have limited English proficiency, disabilities, and cognitive impairments that may add barriers to initiating requests. The commenter lastly recommended that CMS consider eliminating or reducing repayment liability because 2 months of premium liability for this subset of the Medicare population is a relatively small amount in the context of the Medicare program but it can destabilize individuals in this economically fragile population, leading to negative housing and health outcomes that are much more expensive to fix.

Response: We appreciate the thoughtful comments on this topic and share the commenters' concern that drastic reductions in monthly income caused by the collection of back premium charges can jeopardize the health and financial stability of low-income individuals. However, we would need to further explore the operational implications, and have concluded that we would benefit from additional public input. Therefore, we are not finalizing the commenter's recommendations in this final rule. We will consider these comments in development of future rulemaking.

[32] The Northern Mariana Islands are governed by § 407.42.

[33] Under § 435.916(f), if an individual is determined by the State Medicaid agency to no longer meet the eligibility requirements for the eligibility group in which they are enrolled, the State Medicaid agency must determine whether the individual is eligible for Medicaid on a separate basis before proposing to terminate the individual's Medicaid eligibility. While the State is making that determination, the State must maintain Medicaid coverage, which means that, if the individual's eligibility group is included in the State's buy-in agreement, the State must continue pay for the individual's Part B premiums.

[34] Similarly, in cases where an individual is direct billed for premiums, Medicare would bill the individual for up to 2 months' retroactive premiums plus the current month's premium.

h. Revisions to Coordination of Medicaid With Medicare Part B (§ 431.625)

Section 431.625 describes the populations for which Federal financial participation (FFP) is available in expenditures for Part B premiums. Section 431.625(d)(1) identifies the basic rule, which is that FFP is generally unavailable to States for their coverage of Part B premiums, except where such coverage is provided to individuals receiving money payments under title I, IV–A, X, XIV, XVI, or State supplements under section 1616(a) of the Act (optional State supplements) or as required by section 212 of Public Law 93–66 (regarding mandatory State supplements). We proposed updating § 431.625(d)(1) to eliminate the reference to title IV–A, which has been repealed.

Section 431.625(d)(2) lists the exceptions to this basic rule; that is, it lists the Medicaid populations not receiving cash assistance on whose behalf States may both cover their Part B premiums and receive FFP for such coverage. We proposed updating the outdated list of groups in (d)(2) to remove obsolete groups, make technical changes to some remaining groups, and add two additional groups.

Three groups in the current § 431.625(d)(2) are obsolete, and we proposed to remove them from the regulation:

- Paragraph (i): AFDC families eligible for continued Medicaid coverage despite increased income from employment.
- Paragraph (vi): Deemed recipients of AFDC who are participants in a work supplementation program or denied AFDC because the payment would be less than $10.
- Paragraph (x): Individuals no longer eligible for the disregard of $30 or $30 plus one-third of the remainder, but who, in accordance with section 402(a)(37) of the Act, were deemed AFDC recipients for a period of 9 to 15 months.

Due to the proposed deletion of obsolete groups, we proposed to redesignate paragraphs (ii), (iii), (iv), and (v) as paragraphs (i), (ii), (iii), and (iv), respectively; and paragraphs (vii), (viii), and (ix) as paragraphs (v), (vi), and (vii), respectively. We proposed to make the following technical changes to the redesignated paragraphs:

- Redesignated paragraph (i): Delete ''435.114'' which CMS removed from the regulations in the November 2016 final rule.
- Redesignated paragraph (iii): Add cross-references to §§ 435.145 and 436.114(e), which have both been revised since this list was last updated,[35] and modify the description of the group to be consistent with the current description of children with adoption assistance, foster care or guardianship care under title IV–E of the Act.
- Redesignated paragraph (iv): Delete ''chapter'' and add in its place ''subchapter'', for specificity and for consistency with this list.
- Redesignated paragraph (vi): Delete the citation to section 1902(e)(3) of the Act and replace it with a cross-reference to § 435.225, the regulation which implemented section 1902(e)(3) of the Act in November 1990, consistent with other cross-references in this list.
- Redesignated paragraph (vii): Add cross-references to §§ 435.115 and 436.114(f) and (h), both of which CMS revised since last updating the list,[36] and modify the description of the Medicaid eligibility group to reflect the current description of families with extended Medicaid because of increased collection of spousal support under title IV–D of the Act.

While we proposed to eliminate from § 431.625(d)(1) the reference to title IV–A, we cited our belief that we must account for the statutory directive that individuals described in section 1931(b) of the Act be treated for purposes of Title XIX of the Act as receiving title IV–A assistance. We therefore proposed to add to the proposed redesignated paragraph (iii) individuals who are described in section 1931(b) of the Act.

Following the redesignated paragraph (d)(2)(vii), we proposed adding a new paragraph (d)(2)(viii) to include the QMB, SLMB, and QI eligibility groups, as proposed to be defined in § 400.200, to the eligibility groups for which FFP is available. This proposed addition of paragraph (d)(2)(viii) would codify long-standing policy and bring the regulation in alignment with sections 1902(a)(10)(E) and 1905(p)(3) of the Act, which authorize FFP for the State payment of Medicare Part B premiums for all of the MSPs.

In addition, we proposed a new paragraph (d)(2)(ix) to clarify that States receive FFP for Part B payments for adult children with disabilities described in section 1634(c) of the Act. Finally, we made a technical correction in § 431.625(d)(3) to update a cross-reference in the third sentence that is now inaccurate, changing ''435.914'' to ''435.915.''

In the proposed rule (87 FR 25120), we described how the availability of FFP for State expenditures for dually eligible individuals may affect State decisions regarding the breadth of its Part B buy-in coverage group. Sections 1902(a)(10)(E) and 1905 (p)(3)(A) of the Act and the proposed revisions to § 431.625 allow States to obtain FFP not only for Medicare Part B premiums for Medicaid eligibility groups related to cash assistance but for QMB, SLMB, and QI too. We noted that although States cannot obtain FFP for Part B premiums for other Medicaid eligibility groups, paying the premiums for these individuals under buy-in helps States maximize federal funding for health care services.[37]

We did not receive comments on our proposed revisions to regulations addressing Medicaid coordination with Medicare Part B in § 431.625.

i. The Medicare Savings Programs (§§ 435.4, and 435.123 Through 435.126)

In accordance with section 1902(a)(10)(E) of the Act, States must provide medical assistance to certain low-income Medicare beneficiaries. As discussed in detail in the proposed rule (87 FR 25120 through 25122), the four eligibility groups described in section 1902(a)(10)(E) of the Act are generally referred to collectively as the ''Medicare Savings Programs.''

The Medicare Savings Programs include four mandatory eligibility groups. First, we proposed to include the Medicare Saving Programs in the listing in subpart B of part 435 and to add to § 435.4 a definition of the Medicare Savings Programs consistent with section 113 of the Medicare Improvements for Patients and Providers Act (MIPPA), which defines the term Medicare Savings Programs to include the QMB, SLMB, QI, and QDWI eligibility groups.

Second, we proposed to add new § 435.123 to codify the QMB eligibility group under sections 1902(a)(10)(E)(i) and 1905(p)(1) of the Act. As discussed at 87 FR 25121 in the proposed rule, the new § 435.123 (b)(2)(i) and (b)(2)(ii) will

[35] CMS last modified § 435.145 in the November 2016 final rule and last updated § 436.114(e) in the November 21, 1990 **Federal Register** (55 FR 48601), entitled ''Medicaid Program; Eligibility Groups, Coverage, and Conditions of Eligibility; Legislative Changes under OBRA '87, COBRA, and TEFRA,'' (hereinafter referred to as the November 1990 final rule).

[36] CMS last modified § 435.115 in the November 2016 final rule and last changed § 436.114(f) and (h) in the November 17, 1994 **Federal Register** (59 FR 59372), entitled ''Aid to Families with Dependent Children; Extension of Medicaid when Support Collection Results in Termination of Eligibility''.

[37] The proposed rule incorrectly cited section 1905(a)(29)(B) of the Act in support of this statement. The correct citation is section 1903(b)(1) of the Act.

codify in regulation the statutory requirements pertaining to the treatment of a cost of living adjustment (COLA) for Social Security retirement, survivors, and disability benefits in determining eligibility for the QMB, SLMB, and QI eligibility groups. Under section 1905(p)(2)(D) of the Act, income attributable to a Social Security COLA is not countable as income for QMB, SLMB, or QI eligibility purposes during a ''transition month,'' which the statute defines as each month through the end of the month following the month the U.S. Department of Health and Human Services (HHS) publishes the revised official poverty level in the **Federal Register**.

We reminded States they must not wait until CMS notifies them of the new official poverty levels before adjusting their eligibility standards. States must adjust their eligibility standards to reflect the updated poverty level as soon as the Secretary publishes the new poverty level figures in the **Federal Register**. We also included proposed § 435.123(c)(1) and § 435.123(c)(2) reflecting that Medicaid covers premiums and cost sharing for QMBs enrolled in Part B for coverage of immunosuppressive drugs for QMB under section 402 of the CAA, as described in section II of this final rule.

Third, we proposed to add new § 435.124 for the SLMB eligibility group and new § 435.125 for the QI eligibility group described in section 1902(a)(10)(E)(ii) and (iv) of the Act, respectively.

Lastly, we proposed to add a new § 435.126 for the QDWI eligibility group. Paragraphs (a) through (c) of the proposed QDWI provision reflect that, in accordance with sections 1902(a)(10)(E)(ii) and 1905(s) of the Act, QDWI pays the Part A premiums for individuals under age 65 who become entitled to Part A based on their receipt of SSDI, but who subsequently lose SSDI, and as a result, their Part A entitlement, on the basis of gainful employment.

We received the following comment, and our response follows.

Comment: A commenter expressed support for these proposals, particularly with respect to disregarding COLA increases during transition months. The commenter advised that they are aware of States inappropriately terminating MSP coverage due to COLAs without adjusting for updated federal poverty level guidelines.

Response: We thank the commenter for their support. We reiterate that State termination of eligibility during a transition month, by continuing to apply the prior year's poverty level and failing to disregard the COLA, is inconsistent with the statute and harmful to beneficiaries. After considering the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed amendments to § 400.200, § 406.21, § 406.26, § 407.48, § 431.625, and § 435.4 and our proposed additions at §§ 435.124 through 436.126. We are finalizing §§ 407.40 and 435.123 with minor technical revisions to replace references to the resource standard for the Part D Low-Income Subsidy (LIS) Program with citations to the resource levels under section 1905(p)(1)(C) of the Act because section 11404 of the Inflation Reduction Act (IRA) of 2022 (Pub. L. 117–169) delinked the MSP and LIS resource standard starting January 1, 2024, when the LIS standard increases under the law, while the current MSP standard will continue to apply after that date. In addition, in response to comments received, we are finalizing a modified version of § 407.42 to clarify State coverage group options. This modification clarifies that Medicaid-eligible deemed AFDC recipients, if included in State buy-in agreements, must encompass individuals eligible for Medicaid on the basis of section 1931(b) of the Act as well as individuals eligible for Medicaid based on their receipt of adoption assistance, foster care, or guardianship care under Part E of title IV of the Act.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In our April 27, 2022 (87 FR 25090) proposed rule, we solicited public comment on each of these issues for the following provisions that contain information collection requirements. We did not receive any such comments.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2021 National Occupational Employment and Wage Estimates for our salary estimates (*www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 1 presents BLS' mean hourly wage, our estimated cost of fringe benefits and overhead, and our adjusted hourly wage.

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
All Occupations	00–0000	28.01	n/a	n/a

The mean wage under All Occupations applies to a group of respondents that varies widely from working and nonworking individuals and by respondent age, location, years of employment, educational attainment, and other factors. We are not adjusting this figure for fringe benefits and overhead since the individual's enrollment activities will occur outside the scope of their employment, should they be employed.

B. Information Collection Requirements (ICRs)

The following topics are listed in the order of their appearance in section II of this preamble.

1. ICRs Regarding Beneficiary Enrollment Simplification (§§ 406.27 and 407.23)

The following changes will be submitted to OMB for approval under control number 0938–1426 (CMS–10797).

As described in section II.A. of this rule, we are amending §§ 406.27 and 407.23 to provide special enrollment periods (SEPs) for individuals experiencing an exceptional condition to enroll in Medicare premium Part A and Part B. To utilize these new SEPs, an individual will have to submit an enrollment request via a new enrollment form. The form will be used by individuals who have missed an enrollment period due to an exceptional condition to enroll in Part A and/or Part B (see section II.A.2. of this rule for a more detailed discussion).

We estimate that it will take an individual approximately 15 minutes (0.25 hr) at $28.01/hr to complete the form, pull together any required supporting documentation, and submit the completed form to CMS.

Due to the newness of the SEPs, CMS does not have precise data to estimate the number of individuals that may enroll under the new exceptional condition SEPs. However, we believe that the closest equivalent is the number of individuals enrolled during the GEP because the SEPs provide an opportunity to enroll outside of the GEP and we continue to believe that this is the best approach.

TABLE 2—GEP ENROLLMENTS FROM 2016–2021

Year	Individuals enrolling in premium Part A during the GEP	Individuals enrolling in Part B during the GEP	Total Part A and B GEP enrollments
2016	6,546	102,935	109,481
2017	2,021	99,728	101,749
2018	1,819	98,473	100,292
2019	2,223	104,808	107,031
2020	2,221	103,373	105,594
2021	1,918	103,230	105,148
Total	16,748	612,547	629,295
6-Year Average	2,791	102,091	104,882

Based on these data, we estimate that the average number of GEP enrollments per year is 2,791 for premium Part A and 102,091 for Part B (totaling 104,882 annually). We also assume that only a portion of the enrollments would involve an SEP enrollment request since the new SEPs are applicable only for exceptional conditions. In the proposed rule we assumed that 25 percent of individuals who enrolled during the GEP would now be eligible to enroll under an exceptional circumstance SEP.

Based on public comment we are making revisions in this final rule that could increase the number of individuals eligible for an exceptional circumstance SEP, we are increasing the estimated percentage of GEP enrollments transferring to SEP enrollments to 30 percent. As stated previously, we do not have data to estimate projected usage of the exceptional circumstance SEP, but we assume that it will be a small portion of GEP enrollments. We believe that 30 percent is on the high end of projected enrollments but are opting for that amount so as to not underestimate the burden of this provision.

Assuming that 30 percent of individuals who normally would have had to wait until the GEP to enroll will now be eligible using an SEP will result in 31,465 (104,882 enrollments × 0.30) SEP requests annually. As such, we estimate an annual ongoing burden of 7,866 hours (31,465 requests × 0.25 hr/request) at a cost of $220,327 (7,866 hr × $28.01/hr).

We did not receive any comments on the burden of our proposals. As discussed in section II.A. of this proposed rule, we are making the following changes in this final regulation.

- We are revising §§ 406.27(b)(1) and 407.23(b)(1), to specify that the SEP for Individuals Impacted by an Emergency or Disaster is also available if the individual did not live in an area impacted by a Federal, State or local government-declared disaster or emergency, but the individual's authorized representative (as defined at § 405.910), legal guardian, or individual person who makes healthcare decisions on behalf of the individual did. We are also revising §§ 406.27(b)(2) and 407.23(b)(2) to extend the duration of the SEP to 6 months after the end of the emergency declaration. These changes provide flexibility to individuals who are enrolling, or who require assistance enrolling, in Medicare Parts A and B after an emergency or disaster. We do not foresee these revisions affecting our proposed enrollment burden estimates.
- We are revising §§ 406.27(c)(1)(i) and 407.23(c)(1)(i) to include brokers or agents of health plans as entities that may have been a source of misinformation for the SEP for Health Plan or Employer Misrepresentation or Providing Incorrect Information. Originally, we proposed to only include employers and GHPs. Including brokers or agents of health plans as entities that may have been a source of misinformation expands the definition of who is a considered trusted sources of information. Agents and brokers of health plans could be considered as extensions of an individual's health plan and play a critical role in informing individuals of their enrollment options. We are also revising §§ 406.27(c)(1) and 407.23(c)(1) to expressly permit the use of either documentation of misrepresentation or written attestation. Originally, we proposed that written documentation was the only evidence accepted in order to qualify for this SEP. Including a written attestation will ensure that beneficiaries that individuals who receive documentation in forms other than written are not disadvantaged. Lastly, we are revising §§ 406.27(c)(2) and 407.23(c)(2) to increase the duration from 2 months to 6 months to facilitate consistency with the other SEPs. We do not foresee these revisions effecting our proposed enrollment burden estimates.
- We are revising §§ 406.27(d)(2) and 407.23(d)(2) to extend the SEP for Formerly Incarcerated Individuals duration to reflect that the SEP starts the

day of the individual's release from incarceration and ends the last day of the 12th month after the individual is released from incarceration. In addition, we are revising the entitlement date of this SEP at §§ 406.27(d)(3) and 407.23(d)(3) to allow an individual to choose an entitlement date retroactive to the date of their release from incarceration. The changes to extend the SEP duration from 6 months to 12 months and allow for retroactive enrollment will provide formerly incarcerated individuals with additional time to enroll while they are establishing stable conditions and reintegrating into society, as well as the option to have continuous coverage upon release from incarceration. We do not foresee these revisions effecting our proposed enrollment burden estimates.

- We are revising §§ 406.27(e)(3) and 407.23(e)(3) to allow additional opportunities for individuals to choose an entitlement date retroactive to the date of their Medicaid coverage termination. We do not foresee these revisions affecting our proposed enrollment burden estimates.
- We are revising §§ 406.27(f)(2) and 407.23(f)(2) to provide for a minimum duration of 6 months for the SEP for Exceptional Conditions. Originally, we proposed that the duration of the SEP would be determined on a case-by-case basis. We do not foresee these revisions effecting our proposed enrollment burden estimates.
- We have also updated Table 2 at 87 FR 25123 to include 2021 GEP enrollment data. The incorporation of this additional year of data slightly increased the number of projected annual GEP enrollments from 104,829 to 104,882. We accounted for this increase in our calculation previously. We recognize the modifications to the proposed SEPs could result in an increased number of SEP enrollments, however we believe that this increase would be negligible since we are not widening the audience who can be eligible for these SEPs.

2. ICRs Regarding Extended Months of Coverage of Immunosuppressive Drugs for Kidney Transplant Patients (§§ 407.57, 407.59, 407.62, and 407.65)

With regard to this rule's Part B–ID benefit attestation requirements, the following changes will be submitted to OMB for approval under control number 0938–1428 (CMS–10798). With regard to our requirements for terminating the Part B–ID benefit, the following changes will be submitted to OMB for approval under control number 0938–0025 (CMS–1763).

a. Attestations (CMS–10798, OMB 0938–1428)

As described in section II.B of this rule, Congress enacted section 402 of the CAA, amending sections 226A, 1836, 1837, 1838, 1839, 1844, 1860D–1, 1902, and 1905 of the Act to provide immunosuppressive drug coverage for certain individuals whose Medicare entitlement based on ESRD would otherwise end 36 months after the month in which they received a successful kidney transplant. We specified as a condition of enrollment, in §§ 407.57 and 407.59 of this rule and as required in section 402 of the CAA, that an individual must attest that (a) they are not enrolled and do not expect to enroll in coverage described in § 407.55 and (b) they will notify the Commissioner within 60 days of enrollment in such other coverage.

To facilitate deemed enrollment into the Part B–ID benefit, eligible beneficiaries whose coverage will be terminating 36 months after the month of a successful kidney transplant will be provided information about the Part B–ID benefit, and informed that they can enroll in this coverage by attesting that they do not have other excepted coverage and that they will notify the Commissioner of enrollment in such other coverage. We plan to include information about the Part B–ID benefit in the pre-termination notice, as discussed in section II.B.2.b. ''Determination of Eligibility'' of this final rule, and include instructions for individuals to enroll in the Part B–ID benefit, including how to provide the required attestation. We, along with SSA believe that a verbal (telephonic) method will be the most efficient method for a beneficiary to provide the attestation required to enroll in the Part B–ID benefit. It is easily accessible and will avoid potential delays in an individual receiving this vital coverage, as it will not be interrupted or delayed by disruptions in mail or other unforeseen circumstances. If the individual is not amenable to the verbal attestation, they can visit the website address provided to download a PDF-fillable version of the form to submit to SSA, or call SSA to request a paper form.

We received many comments on our proposed methods of attestation for the Part B–ID benefit, but we did not receive comments on our burden estimates. Commenters supported CMS' approach to allow individuals to use various methods to attest to their eligibility and enroll in the Part B–ID benefit, and several commenters recommended that CMS consider additional methods of attestation, particularly electronic submission, fax, or other signed documents. Those comments and our responses are in section II.B.2. ''Part B–ID Benefit Eligibility, Enrollment, Entitlement, and Termination'' of this final rule. In consideration of those public comments, and to provide for flexibility for other attestation methods in the future, we are revising § 407.59 to provide for additional attestation methods (that is, electronic submission or fax).

The attestation options will also be available for individuals who were previously terminated from Medicare based on ESRD after 36 months, or individuals who are reenrolling into the Part B–ID benefit for coverage of immunosuppressive drugs.

We expect that the population of individuals eligible for the Part B–ID benefit will use all available options: telephonic attestation, completion and submission of website-accessed PDF-fillable forms, and completion of paper forms requested from CMS or SSA, (and eventually fax and online) to provide the required attestation to SSA. We expect that each of the options for providing the required attestation, including future fax or online options, will require approximately the same burden. We estimate that individuals attesting telephonically or via a paper or PDF attestation form, (as well as future fax or online options), will have the same time of 10 minutes (0.167 hr) per response.

CMS's Office of the Actuary (OACT) expects an average of 767 individuals, whose Medicare entitlement based on ESRD which ended 36-months after the month in which they received a successful kidney transplant, to request enrollment in the Part B–ID benefit from 2023 through 2025. This estimate was provided by CMS actuaries based on historical information provided by SSA on the number of individuals who had prior Medicare Part A coverage and a kidney transplant between 2001 and 2019, and then making downward adjustments to account for those individuals who are deceased or who are anticipated to have other comprehensive coverage and will not be eligible for the Part B–ID benefit. The overall results of applying these assumptions is that roughly 1,800 individuals would be enrolled in the Part B–ID benefit in 2023, with an estimated growth of 250 enrollees each year thereafter. This would equate to approximately 2,300 individuals (1,800 in 2023 + 250 in 2024 + 250 in 2025) enrolling in the Part B–ID benefit from 2023 through 2025, or an annual estimated enrollment of 767 individuals

(2,300 individuals/3 years). The burden associated with the Part B–ID benefit is the time required to complete and submit an attestation. We estimate a total annual burden of 128 hours (767 Part B–ID enrollees * 0.167 hr/response) at a cost of $3,585 (128 hr * $28.01/hr).

b. Termination of the Part B–ID Benefit (CMS–1763, OMB 0938–0025)

In § 407.62 of this rule, individuals can voluntarily terminate their Part B–ID benefit at any time by notifying SSA. Primarily, an individual will contact SSA to request termination, either telephonically, or by visiting an SSA field office. If an individual is not amenable to contacting SSA to terminate their Part B–ID benefit, they can access the CMS or SSA website and print, sign and mail the form to SSA, or call SSA to request a paper form to submit their request. We expect that all available options (SSA contact, completion and submission of website-accessed form, and completion of paper form requested from CMS or SSA) to request a termination from the Part B–ID benefit will be used by beneficiaries. We expect that each of the options for requesting a termination from the Part B–ID benefit will require approximately the same burden, namely 10 minutes (0.167 hr) per response.

Currently, individuals who are requesting termination of premium Hospital Insurance (Part A) or termination of Supplementary Medical Insurance (Part B) or both can complete the Request for Termination Form (CMS–1763). While we are revising the form to include termination of the Part B–ID benefit, we are not changing our currently approved per response time estimate of 10 minutes (0.167 hr) per response.

We have limited means of estimating how many individuals will opt to terminate their Part B–ID benefit as this immunosuppressive drug benefit is yet to be implemented—the statutory effective date is January 1, 2023. However, for estimation purposes, we assume an average of 10 percent of the individuals enrolled in the Part B–ID benefit will voluntarily disenroll. As discussed in section III.B.2.a. of this final rule, OACT estimates that approximately 767 eligible individuals will enroll in the Part B–ID benefit annually from 2023–2025, we estimate that 77 of these individuals (767 eligible individuals × 0.10) will voluntarily terminate their Part B–ID benefit. This does not include individuals who are involuntarily terminated from the Part B–ID benefit because CMS or SSA determined that they had other coverage that made them ineligible for the Part B–ID benefit, or because they failed to pay the required premium. Also excluded from this number are individuals who will obtain Medicare coverage based on age, disability, or ESRD status, and therefore, will not remain enrolled in the Part B–ID benefit, and individuals who die. Our methodology was to estimate the total Part B terminations as a percent of total Part B enrollments annually from 2019–2021 (about 3 percent).[38] We then assumed that the Part B–ID benefit terminations would be more frequent, as we anticipate that individuals may explore options available for more comprehensive coverage, given an individual's other post-transplant associated expenses. Therefore, we increased that percentage from 3 percent to 10 percent. We then used OACT's growth estimate of 767 enrollments annually between 2023 and 2025 to estimate that 10 percent of those enrollments, or approximately 77 annually, would terminate their Part B–ID benefit voluntarily.

Based on voluntary terminations of the Part B–ID benefit only, by the methods described previously, we expect a total annual burden of 13 hours (77 requests to terminate the Part B–ID benefit × 0.167 hr) at a cost of $364 (13 hr × $28.01/hr) per year. Although, we have limited means to determine the actual number of individuals who will terminate their coverage, as we implement this benefit we will have data to better adjust (if/when needed) our burden estimates in the future.

c. Reporting of MSP Part B–ID Benefit Enrollment Information (CMS–10143, OMB 0938–0958) and (CMS–R–284, OMB 0938–0345)

As described in section II.B.3. of this final rule, under section 402(f) of the CAA, we proposed to modify three Medicare Savings Programs (MSP) eligibility groups (Qualified Medicare Beneficiary (QMB), Specified Low-Income Medicare Beneficiary (SLMB) and Qualifying Individual (QI)) to pay premiums and, if applicable, cost sharing for low-income beneficiaries enrolled in Part B–ID (MSP Part B–ID). Under the MSP Part B–ID benefit, States will pay the Part B–ID benefit premiums and cost sharing for QMBs, and Part B–ID benefit premiums for SLMBs and QIs.

Once States enroll individuals in an MSP Part B–ID benefit, States will need to report the enrollment information to CMS. As discussed in our April 27, 2022, proposed rule (87 FR 25125), we anticipated enrollment in a MSP Part B–ID benefit mainly occurring in the 12 States that, as of December 2021, have elected to not expand Medicaid eligibility to adults with income up to 138 percent of the FPL (''non-expansion States'') and among QMB individuals in these States who fall into the coverage gap—that is individuals whose income prevents them from receiving Medicaid coverage, but is too low to qualify for advanced premium tax credit (APTC) or cost sharing reduction (CSR) in the Exchange. Based on reviewing internal data from 2021 to determine how many individuals were enrolled in MSPs, had Medicare entitlement based on ESRD, and were 36 months post-transplant and our actuaries' estimate, we anticipated only 250 individuals per year enrolling in the Part B–ID benefit, all of whom will enroll through the QMB Part B–ID benefit. Because we anticipated all of these individuals will initially be enrolled in MSPs and simply convert over to an MSP Part B–ID benefit when they lose Medicare entitlement based on ESRD and then enroll in the Part B–ID benefit, we did not anticipate that there will be any new or revised burden for these enrollees to apply for a MSP Part B–ID benefit other than the initial enrollment in the Part B–ID benefit. Rather, the burden for enrolling these individuals will fall on the State when it is performing a redetermination of Medicaid eligibility. As described in section II.B.3. of this rule, when an individual loses Medicaid eligibility, a State must already perform a redetermination under all categories of eligibility per § 435.916(f)(1). As such, we did not anticipate any new or revised burden on States enrolling these individuals either. We also anticipated that there would not be any new or revised reporting burden on States for the MSP Part B–ID benefit because individuals would receive coverage under existing MSP eligibility groups. States already submit enrollment information for all current MSP enrollees through the Medicare Modernization Act (MMA) under control number 0938–0958 (CMS–10143) and the Transformed Medicaid Statistical Information System (T–MSIS) under control number 0938–0345 (CMS–R–284) files, and we did not anticipate including the new MSP Part B–ID benefit enrollees in the MMA and T–MSIS file submissions to CMS would result in any new burden. For the MMA file, we proposed to inform States to report MSP Part B–ID benefit enrollees using the exact same code as for any other MSP enrollee, but that CMS would determine MSP Part B–ID benefit enrollment by examining both the MSP code and the Medicare enrollment reason code. For the T–MSIS file, we

[38] Data source: ELMO, 12/3/2021.

proposed to inform States to report MSP Part B–ID benefit enrollees using the exact same code as for any other MSP enrollee, but to fill in a different value for another field. Because we expected no coding changes to either MMA or T–MSIS files, we did not anticipate that any system changes would be necessary for submitting these files to CMS.

We did not receive any comments indicating that there would be any new burden. As a result, we are finalizing our assumptions as proposed.

3. ICRs Regarding Simplifying Regulations Related to Medicare Enrollment Forms (§§ 406.7 and 407)

As described in section II.C. of this rule, we are revising §§ 406.7 and 407.11 to remove all references to specific enrollment forms that are used to apply for entitlement under Medicare Part A and enrollment under Medicare Part B. This is an administrative change that has no impact on the use or availability of these forms and has no effect on any of our currently approved information collection requirements or burden estimates. We are removing references to the following enrollment forms that are currently OMB approved and are still in use under the approved scope:

- Medicare Part A Enrollment Forms (§ 406.7)

++ CMS–18–F–5 (OMB 0938–0251)—Application for Hospital Insurance Entitlement

++ CMS–43 (OMB 0938–0080)—Application for Health Insurance Benefits under Medicare for Individuals with End Stage Renal Disease (ESRD)

- Medicare Part B Enrollment forms (§ 407.11)

++ CMS–18–F–5 (OMB 0938–0251)—Application for Hospital Insurance Entitlement

++ CMS–4040 (OMB 0938–0245)—Application for Enrollment in the Supplementary Medical Insurance Program.

++ CMS–40–B (OMB 0938–1230)—Application for Enrollment in Medicare Part B (Medical Insurance)

++ CMS–40–D [39]—Application for Enrollment in the Supplementary Medical Insurance Program.

++ CMS–40–F [40]—Application for Medical Insurance

We did not receive any comments on our proposal and are finalizing the change as proposed.

C. Summary of Annual Burden Estimates for Finalized Changes

TABLE 3—ANNUAL REQUIREMENTS AND BURDEN ESTIMATES

Regulation section(s) under Title 42 of the CFR	OMB control No. (CMS ID No.)	Respondents	Total responses	Time per response (hours)	Total time (hours)	Labor cost ($/hr)	Total cost ($)
§§ 406.27 and 407.23	0938–1426 (CMS–10797)	31,465	31,465	0.25	7,866	28.01	220,327
§ 407.59	0938–1428 (CMS–10798)	767	767	0.167	128	28.01	3,585
§ 407.62	0938–0025 (CMS–1763)	77	77	0.167	13	28.01	364
Total		32,309	32,309	Varies	8,007	28.01	224,276

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule implements certain Medicare-related provisions of the CAA, as well as propose other enrollment-related changes. Section 120(a)(1) of the CAA revised the entitlement periods for individuals who enroll in Medicare Part B in the last 3 months of their IEP, deemed IEP, or during the GEP, beginning January 1, 2023. Under longstanding Medicare rules, the effective date of entitlement varies depending on whether the individual is enrolling during the IEP or GEP and when an enrollment is made during each specific enrollment period which could cause confusion. The changes should help eliminate this potential confusion by establishing a straightforward and uniform policy regarding Part A and Part B entitlement start dates.

Section 120 of the CAA also gives the Secretary the authority to establish SEPs for exceptional conditions. Under current rules, individuals are only able to enroll outside of the IEP or GEP either through States enrolling them through the buy-in process under section 1843 of the Act or by using a limited number of SEPs and, outside of that, relief is only available in instances where an individual did not enroll due to a Federal Government error. Other than these very specific scenarios, no exceptions are legally permissible.

The changes give the Secretary the flexibility to address other situations where a beneficiary missed an enrollment period and mirrors the authority that has long been available under the Medicare Part C and Part D programs. We believe this provision is likely to improve access to continuous coverage for individuals covered by Medicare Part A and Part B, either through expediting the effective date of coverage or by allowing for opportunities to enroll in coverage sooner. Therefore, we anticipate this change having a positive impact on communities who experience social risk factors impacted by lack of continuous health coverage. Our changes fulfill the goals of the January 28, 2021. *Executive Order on Advancing Racial Equity and Support for Underserved Communities through The Federal Government,* which directs the Secretary of the Department of Health and Human Services, among other things, to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.[41]

Further, section 402 of the CAA extends immunosuppressive drug coverage for individuals whose Medicare entitlement based on ESRD ends 36-months after the month in which they received a successful kidney transplant by providing immunosuppressive drug coverage under Medicare Part B for certain individuals. Under current rules, an individual loses Medicare coverage 36 months after a successful transplant (unless they are otherwise entitled to the coverage), but it does not negate the need for an individual to take immunosuppressive drugs long-term. Not having coverage for immunosuppressive drugs can cause individuals to reduce their usage in order to make their medication last longer or they may stop taking the medications entirely which can lead to organ rejection and transplant failure. The new Part B–ID benefit helps remedy

[39] CMS–40–D became obsolete in 3/2022.

[40] CMS–40–F became obsolete in 2008.

[41] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

this situation by ensuring that these individuals have access to immunosuppressive drug coverage potentially for the rest of their life. Even with access to immunosuppressive drug benefits, low-income individuals may be unable to afford these immunosuppressive drugs due to their high cost. By extending certain MSP programs to this new Part B–ID benefit, States will cover the costs of the Part B–ID premiums and in some cases, cost sharing as well. In particular, this MSP Part B–ID coverage will help individuals who lose Medicare coverage 36 months after a successful transplant and live in a non-expansion State with income too high to receive subsidies for purchasing a health plan in the Exchange. Without this MSP Part B–ID coverage, these individuals may be unable to pay Part B–ID premiums and cost sharing and as such, at higher risk of transplant failure. As such, supporting continued Medicaid coverage is consistent with the *Executive Order on Strengthening Medicaid and the Affordable Care Act* and the *Executive Order on Continuing to Strengthen Americans' Access to Affordable Quality Health Coverage.*

In addition to implementing various sections of the CAA, we sought to modernize the Medicare Savings Programs through which States cover Medicare premiums and cost sharing and updated the various federal regulations that affect a State's payment of Medicare Part A and B premiums for beneficiaries enrolled in the Medicare Savings Programs and other Medicaid eligibility groups. We believe that it is important to update these policies to reflect statutory changes over the last 3-plus decades as well as to codify certain administrative practices that have evolved over the years. We anticipated our proposals would also advance health equity by improving low income individuals' access to continuous, affordable health coverage and use of needed health care consistent with the *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.* We also expected that our proposals would improve the customer service experience of dually eligible beneficiaries consistent with the goals of the *Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government.* These are commonsense, good government proposals that would also reduce administrative burden on States and promote transparency and clarity regarding State payment of premiums or buy-in.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). These final regulations are not economically significant within the meaning of section 3(f)(1) of Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these regulations, and the Department has provided the following assessment of their impact.

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million annually. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities. This rule's costs will predominantly fall on the Federal government and States, and the associated burden falls primarily on the Federal government and individuals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This final rule will not result in expenditures that meet or exceed this amount.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule will not have a substantial direct effect on state or local governments.

C. Detailed Economic Analysis

1. Beneficiary Enrollment Simplification (§§ 406.22 and 407.23)

We are revising regulations to implement section 120 of the CAA. These revisions make the effective date of coverage the first of the month following an individual's enrollment during their IEP or during the GEP. We are also establishing SEPs that will provide individuals who meet certain exceptional conditions an opportunity to enroll without having to wait for the GEP.

a. Benefits

The changes to the IEP and GEP coverage dates provide Medicare beneficiaries access to coverage more quickly and may allow them faster access to needed medical care. The new SEPs for beneficiaries who have experienced an exceptional condition that caused them to delay enrollment in

Medicare also provide access to Medicare coverage earlier, reducing gaps in coverage, and beneficiaries may avoid LEPs by utilizing these SEPs.

b. Costs

Costs include increased months of coverage provided by the new SEPs and the earlier effective dates for the IEP and GEP and potential loss of LEP revenue. As detailed earlier, we estimate that approximately 31,449 individuals would be eligible to enroll earlier using the exceptional condition SEPs.

In addition, CMS does not foresee an increase of costs to Medicare beneficiaries related to Part B premium increases. Specifically, we do not expect beneficiaries enrolling under these new provisions to have higher-than-average costs, so we assume this provision will not have an impact on the Part B premium.

c. Transfers

The CAA also modified section 1839(b) of the Act to exempt individuals who enroll pursuant to an SEP for exceptional conditions established under section 1838(m) of the Act, from paying an LEP. Therefore, beneficiaries who are able to utilize the newly established SEPs will benefit from an avoidance of an LEP. Based on the data described in section III B.1 of this final rule, we estimate approximately 31,449 premium Part A and Part B enrollments annually under the new SEPs. We anticipate that the loss of revenue associated with LEP and the additional months of coverage associated with individuals using the new SEPs will be a cost to the Medicare Trust Fund. Due to variables that CMS cannot predict, such as the timing of when beneficiaries will use an SEP to enroll in Medicare or what their LEP would have been had the SEP not been made available, CMS is not able to estimate an exact cost to the Trust Funds that will result from enrolling beneficiaries through SEPs. However, based on the small number of beneficiaries impacted, and because this rule allows that individuals will have to miss an enrollment period in order to access these new SEPs, we expect the increased costs to the Medicare to be negligible, even considering the modifications to the SEPs in the final rule as we believe these changes will have a negligible impact on the use of the new exceptional conditions SEPs. Further, we note the beneficiaries who are enrolled via these SEPs would be paying premiums to the Trust Fund, which would be revenue that might have otherwise gone uncollected.

2. Extended Months of Coverage of Immunosuppressive Drugs for Kidney Transplant Patients (§§ 407.1, 407.55, 407.57, 407.59, 407.62, 407.65, 408.20, and 423.30)

We are revising regulations that would establish the new Part B–ID benefit. These regulations would establish the eligibility requirements (including the requirement that the individual attest that they do not have other disqualifying health coverage), the reasons and process for termination of coverage, and the basis for the premium for the benefit.

a. Benefits

The American Society of Nephrology and the HHS Assistant Secretary for Planning and Evaluation report that providing beneficiaries with extended access to immunosuppressive drugs may reduce any associated costs they face from kidney failure, including maintaining labor force participation and improved quality of life.[42]

b. Costs

Extending immunosuppressive drug coverage will pose an additional cost to Medicare to pay for the additional drugs, reduced by the savings associated with reduction in reversion to dialysis from graft failure. CMS actuaries estimate a net cost of $55 million to the Medicare program over the period 2022–2031. This estimate was provided by CMS actuaries, based on historical information from SSA. SSA's data shows that roughly 165,000 individuals had prior Medicare Part A coverage and had a kidney transplant between 2001 and 2019. Removing any individuals not currently alive or enrolled in Medicare Part A, within SSA's historical data approximately 52,000 individuals would remain potentially eligible to enroll in Part B–ID. In addition, CMS assumes approximately 1,000 individuals a month will be disenrolled from Medicare Part A 36 months after a successful transplant. After accounting for those individuals who are anticipated to have other coverage, and thus would not be eligible for the Part B–ID benefit, we assume that of those who were terminated from Part A after a successful transplant between 2001 and 2019, roughly 1,050 individuals would initially be enrolled in the Part B–ID benefit. Using similar assumptions about other coverage and those that are newly eligible for the benefit (roughly 12,000 individuals in a year), we assume an estimated growth of 250 enrollees each year thereafter. Beneficiaries will also incur potential costs associated with the premium associated with the additional benefit. For beneficiaries enrolled in MSPs for coverage of premiums and cost sharing of the Part B–ID benefit, States will incur premium and cost sharing costs for the benefit as well as costs associated with systems and other changes needed for reporting enrollment in these MSPs as described in further detail elsewhere in this document.

The following table titled Part B–ID Benefit Costs and Savings Estimate demonstrates the year by year amounts, broken out by cost for drugs and savings.

TABLE 4—PART B–ID BENEFIT COSTS AND SAVINGS ESTIMATE

[in $ millions]

FY	Cost due to drugs	Savings due to saved transplants	Total gross benefits	Part B premium offset	Net impact
2022	0	0	0	0	0
2023	0	0	0	0	0
2024	5	0	5	0	5
2025	5	0	5	0	5
2026	5	0	5	0	5
2027	5	0	5	0	5
2028	10	0	10	−5	5

[42] Kadatz, M., Gill, J. S., Gill, J., Formica, R. N., and Klarenbach, S. (2019). Economic Evaluation of Extending Medicare Immunosuppressive Drug Coverage for Kidney Transplant Recipients in the Current Era. Journal of the American Society of Nephrology, 31(1), 218–228. *https://doi.org/10.1681/asn.2019070646.* See *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/189276/Savings_From_Extending_Coverage_For_Immunosuppressive_Drugs_Final.pdf* from ASPE discussing cost benefits of extending drug coverage.

TABLE 4—PART B–ID BENEFIT COSTS AND SAVINGS ESTIMATE—Continued

[in $ millions]

FY	Cost due to drugs	Savings due to saved transplants	Total gross benefits	Part B premium offset	Net impact
2029	10	0	10	0	10
2030	10	0	10	0	10
2031	15	0	15	−5	10

c. Effects of Medicare Saving Programs Coverage for Immunosuppressive Drugs

As described previously, under section 402(f) of the CAA, we proposed to modify three MSP eligibility groups (QMB, SLMB, and QI) to pay premiums and, if applicable, cost sharing for low-income beneficiaries enrolled in the Part B–ID benefit (MSP Part B–ID). Individuals currently enrolled as QMBs, SLMBs, and QIs must meet income and resource requirements in addition to having entitlement to Medicare Part A. With this change, individuals may enroll in QMB, SLMB, and QI for the Part B–ID benefit if they are enrolled in the Part B–ID benefit and meet the underlying income and resource requirements for QMB, SLMB, or QI. While States pay Medicare Part A and B premiums and cost sharing for certain MSP eligibility groups, State payment for the MSP Part B–ID benefit is limited to Part B–ID benefit premiums and/or cost sharing.

As discussed in more detail in section II.B.3 of this final rule, due to the limited scope of Part B–ID benefit entitlement and the income and resource eligibility limits for the MSP population, we anticipated enrollment in the MSP Part B–ID benefit mainly occurring in the 12 non-expansion States among individuals who qualify as QMBs, with about 250 people a year enrolling and 1,000 people enrolling initially. We estimated the cost of paying for the Part B–ID benefit for these individuals across all States was −$657,000 (1,250 × (State portion of premium (Part B–ID benefit premium ($1,200) × States' average FMAP rate) (1–0.562)) + State portion of Part B–ID benefit cost sharing (20 percent of cost of CMS actuarial estimate of immunosuppressive drug therapy ($8,000 × 0.2) × States' average FMAP rate (1 − 0.562) − Medicaid drug rebate of 50 percent of cost of immunosuppressive drug therapy ($8,000 × 0.5) × States' average FMAP rate (1 − 0.562). In sum, we estimated the drug rebate more than offsetting the State share of the Part B–ID benefit premium and cost sharing obligations, yielding a net savings for States.

In addition to the liability for the Part B–ID benefit premium and cost sharing, we estimated States would need to perform the following tasks: (1) modify their systems to report MSP Part B–ID benefit enrollment on the Third Party Systems (TPS) files; (2) modify their internal systems to receive and process new values in existing fields for Part B–ID benefit enrollment in the MMA file, TPS, Territories and States Beneficiary Query (TBQ), T–MSIS, as well as on SSA's state data exchanges; (3) process the change in the premium from the Part B standard premium to the Part B–ID benefit premium in TPS for billing; (4) modify their process to query SSA systems to confirm Part B–ID benefit enrollment prior to enrolling in the MSP Part B–ID benefit; (5) adjust Medicaid eligibility systems to include new MSP Part B–ID benefit enrollment codes; and (6) adjust Medicaid pharmacy claims to include this new Part B–ID benefit crossover claim. We anticipated all States would need to make systems changes and test these systems changes 4–6 months prior to implementation.

We estimated that it would take a maximum of 12 months of work (approximately 2,000 hours) by three computer programmers working $92.92/hr to make the necessary systems changes. Since we estimated that 50 states plus the District of Columbia (DC)[43] will need to make a plan for system changes, we projected an aggregate burden of $12,510,748.8 (51 (50 States and DC) * 2,000 hr * $92.92/hr * 3 * States' average FMAP rate). We noted that the cost and time attributable to these systems change would be influenced by whether the state is implementing other systems changes at the same time and their current Medicaid Management Information System (MMIS) system functionality. Assuming the state implements this change in isolation, we estimated that this change could take 12 months. However, if a State makes this change as a part of a broader systems update, the work specific to the proposal could be less burdensome.

We did not receive any comments on these estimates and are finalizing as proposed.

3. Simplifying Regulations Related to Medicare Enrollment Forms

We are revising §§ 406.7 and 407.11 to remove references to specific enrollment forms that are used to apply for entitlement under Medicare Part A and enrollment under Medicare Part B. This is an administrative change that will not impact the use of the forms. We do not anticipate a change in burden or cost associated with each of the forms.

4. Modernizing State Payment of Medicare Premiums Benefits, Costs, and Transfers

To modernize State payment of Medicare premiums, we proposed several changes to regulations at §§ 400.200, 406.21, 406.26, 407.40 through 48, and 431.625. We also proposed to add new §§ 435.123 through 435.126 and to revise § 435.4. Almost all of the proposed changes were to update the regulations to reflect statutory changes over the last 3-plus decades, and to codify certain administrative practices that have evolved over the years. Some of the most significant changes included replacing obsolete decades-old stand-alone buy-in agreements with treating buy-in provisions in the State plan as the State's buy-in agreement, and limiting retroactive Medicare Part B premium liability for States for full-benefit dually eligible beneficiaries. We did not project any impact for these provisions in this Regulatory Impact Analysis section because our proposals were consistent with current requirements and practice.

We did not receive any comments on these estimates and are finalizing as proposed.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due

[43] We note that we did not estimate impacts for the territories because currently, they have not elected MSP coverage for their residents. As such, they would not need to make these changes.

to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. We welcomed any public comments on the approach in estimating the number of entities that would review the proposed rule. We did not receive any public comments specific to our solicitation.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule, and therefore for the purposes of our estimate we assumed that each reviewer reads approximately 50 percent of the rule. We sought public comments on this assumption. We did not receive any public comments specific to our solicitation.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $115.22/hr, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 0.5 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is $57.61 (0.5 hours × $115.22/hr). Therefore, we estimate that the total cost of reviewing this rule is $4,032.70 ($57.61 × 70) [*70 is the number of estimated reviewers*].

E. Alternatives Considered

As noted previously, there were a number of additional SEPs that were considered but were not pursued for various reasons (discussed in greater length in section II.A.2.f of the preamble). For example, we considered an SEP for individuals who previously decided not to enroll in Medicare but now want to enroll outside of the GEP or other enrollment period because they are experiencing a health event and want Medicare coverage. We also considered an SEP for individuals who lost Medicare coverage solely due to non-payment of premiums who are not eligible for another SEP or equitable relief and now want to re-enroll outside of the GEP.

In addition, we considered finalizing the SEPs as proposed rather than making the changes based on comments in this final rule. Specifically, we considered keeping the SEP for individuals impacted by an emergency or disaster to only apply if the individual themselves were impacted rather than allowing them to qualify if they are prevented from enrolling in Medicare because the person who helps them make health care decisions resides in area where there is a federal, state, or local disaster declaration. In addition, we considered finalizing the SEP for Health Plan or Employer Error as proposed rather than modifying it to allow an individual to qualify for the SEP if they received erroneous or misinformation from agents and brokers in addition to health plans and employers and to provide a written attestation of the error. Finally, we considered maintaining the 6-month duration for the SEP for Formerly Incarcerated Individuals rather than changing the duration to 12 months and not allowing the option to choose retroactive or prospective coverage. Had we finalized these SEPs as proposed, we estimate that slightly fewer individuals would be able to enroll using the exceptional conditions SEPs, as each of the changes in this final rule will ease access to the SEPs either through increasing the timeframe or opportunities to qualify for the SEPs.

Further, we proposed several alternatives to the State payment of Medicare premium policies and technical changes, which are described at 87 FR 25112 through 25122. For example, we considered alternatives to further reduce the number of Part B buy-in groups from three to two and to limit buy-in liability for States in other situations in which Medicare benefits are not available, such as incarceration and beneficiaries who reside overseas. In addition, we considered proposing limits on State premium liability for time periods longer or shorter than 36 months, including a range from 24 to 60 months. Based on CMS data from 2022, an average of about 147,000 Medicaid beneficiaries are newly enrolled in Part B buy-in each month. Over a 6-month period, an average of 2,244 Medicaid beneficiaries per month were retroactively enrolled in Part B buy-in for more than 12 months, 1,138 were retroactively enrolled for more than 24 months, 720 were retroactively enrolled for more than 36 months, 517 were retroactively enrolled for more than 48 months, and 393 were retroactively enrolled for more than 60 months.

D. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 5 showing the classification of the impact associated with the provisions of this final rule.

TABLE 5—ACCOUNTING STATEMENT

[in $ millions]

Category	Estimate at 7% (in 2022 dollars)	Estimate at 3% (in 2022 dollars)	Period	Affected stakeholders
Annualized Monetized Savings	$0	$0	2022–2031	Federal government, States.
Annualized Monetized Cost	0.39	0.06	2022–2031	Federal government, States.

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 17, 2022.

List of Subjects

42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO) Medicaid,

Medicare Reporting, and recordkeeping requirements.

42 CFR Part 406

Health facilities, Diseases, and Medicare.

42 CFR Part 407

Medicare.

42 CFR Part 408

Medicare.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and, recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), and Wages.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 400—INTRODUCTION; DEFINITIONS

■ 1. Effective January 1, 2023, the authority citation for part 400 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh and 44 U.S.C. Chapter 35.

■ 2. Effective January 1, 2023, § 400.200 is amended by—

■ a. Adding a definition for ''Medicare Savings Programs'' in alphabetical order;

■ b. Revising the definition of ''Qualified Medicare Beneficiary''; and

■ c. Adding definitions for ''Qualifying Individual'' in alphabetical order and ''Specified Low-Income Medicare Beneficiary'' in alphabetical order.

The additions and revision read as follows:

§ 400.200 General definitions.

* * * * *

Medicare Savings Programs (MSPs) has the same meaning described in § 435.4 of this chapter.

* * * * *

Qualifying Individual (QI) means an individual described in § 435.125 of this chapter.

Qualified Medicare Beneficiary (QMB) means an individual described in § 435.123 of this chapter.

* * * * *

Specified Low-Income Medicare Beneficiary (SLMB) means an individual described in § 435.124 of this chapter.

* * * * *

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

■ 3. Effective January 1, 2023, the authority citation for part 406 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395i–2, 1395i–2a, 1395p, 1395q and 1395hh.

■ 4. Effective January 1, 2023, § 406.7 is revised to read as follows:

§ 406.7 Forms to apply for entitlement under Medicare Part A.

Forms used to apply for Medicare entitlement are available free of charge by mail from CMS or at any Social Security branch or district office or online at the CMS and SSA websites. An individual who files an application for monthly social security cash benefits as defined in § 400.200 of this chapter also applies for Medicare entitlement if he or she is eligible for hospital insurance at that time.

■ 5. Effective January 1, 2023, § 406.13 is amended by revising paragraph (f)(2) to read as follows:

§ 406.13 Individual who has end-stage renal disease.

* * * * *

(f) * * *

(2) The end of the 36th month after the month in which the individual received a kidney transplant. Beginning January 1, 2023, an individual who is no longer entitled to Part A benefits due to this paragraph may be eligible to enroll in Part B solely for purposes of coverage of immunosuppressive drugs as described in § 407.55 of this subchapter.

* * * * *

■ 6. Effective January 1, 2023, § 406.21 is amended by revising paragraphs (a) and (c)(3) to read as follows:

§ 406.21 Individual enrollment.

(a) *Basic provision.* An individual who meets the requirements of § 406.20(b) or (c), except as provided in § 406.26(b)(2), may enroll for premium hospital insurance only during his or her—

(1) Initial enrollment period as set forth in paragraph (b) of this section;

(2) A general enrollment period as set forth in paragraph (c) of this section;

(3) A special enrollment period as set forth in §§ 406.24, 406.25, and 406.27; or

(4) For HMO/CMP enrollees, a transfer enrollment period as set forth in paragraph (f) of this section.

* * * * *

(c) * * *

(3) If the individual enrolls or reenrolls during a general enrollment period—

(i) Before January 1, 2023, his or her entitlement begins on July 1 of the calendar year; or

(ii) On or after January 1, 2023, his or her entitlement begins on the first day of the month after the month of enrollment.

* * * * *

■ 7. Effective January 1, 2023, § 406.22 is amended by—

■ a. Removing the phrase ''age 65, the following rules apply:'' and adding in its place the phrase ''age 65, before January 1, 2023, the following rules apply:'' in paragraph (a) introductory text;

■ b. Redesignating paragraph (b) as paragraph (c);

■ c. Adding a new paragraph (b);

■ d. Revising newly redesignated paragraph (c) introductory text; and

■ e. Adding paragraph (d).

The additions and revision read as follows:

§ 406.22 Effect of month of enrollment on entitlement.

* * * * *

(b) *Individual age 65 or over.* For an individual who has attained age 65 on or after January 1, 2023, the following rules apply:

(1) If the individual enrolls during the first 3 months of their initial enrollment period, entitlement begins with the first month of eligibility.

(2) If an individual enrolls during the last 4 months of their initial enrollment period, entitlement begins with the month following the month of enrollment.

(c) *Individual under age 65.* For an individual who has not attained age 65 and who satisfies the requirements of § 406.20(c) before January 1, 2023, the following rules apply:

* * * * *

(d) *Individual under age 65.* For an individual who has not attained age 65 and who first satisfies the requirements of § 406.20(c) on or after January 1, 2023, the following rules apply:

(1) For individuals who enroll during the first 3 months of their IEP,

entitlement begins with the first month of eligibility.

(2) If an individual enrolls during the month in which they first become eligible or any subsequent month of their IEP, entitlement begins with month following the month of enrollment.

■ 8. Effective January 1, 2023, § 406.26 is amended by adding paragraph (a)(3) and revising paragraph (b)(2) to read as follows:

§ 406.26 Enrollment under State buy-in.

(a) * * *

(3) *Enrollment without discrimination.* A State that has a buy-in agreement in effect must enroll in premium health insurance any applicant who meets the eligibility requirement for the QMB eligibility group, with the State paying the premiums on the individual's behalf.

(b) * * *

(2) The first month in which the individual is entitled to premium hospital insurance under § 406.20(b) and has QMB status. Under a State buy-in agreement, as defined in § 407.40 of this subchapter, QMB-eligible individuals can enroll in premium hospital insurance at any time of the year, without regard to Medicare enrollment periods.

* * * * *

■ 9. Effective January 1, 2023, § 406.27 is added to read as follows:

§ 406.27 Special enrollment periods for exceptional conditions.

(a) *General rule.* Beginning January 1, 2023, in accordance with the Secretary's authority in sections 1837(m) and 1838(g) of the Act, the following SEPs, as defined under § 406.24(a)(4), are provided for individuals that missed a Medicare enrollment period, (as specified in § 406.21, § 406.24, or § 406.25), due to exceptional conditions as determined by the Secretary and established under paragraphs (b) through (f) of this section. SEPs are provided for exceptional conditions that took place on or after January 1, 2023 except as specified in paragraph (e) of this section.

(b) *Special enrollment period for individuals impacted by an emergency or disaster.* An SEP exists for individuals prevented from submitting a timely Medicare enrollment request by an emergency or disaster declared by a Federal, State, or local government entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they (or their SSA-authorized representative as defined at 42 CFR 405.910), their legal guardian, or person who makes healthcare decisions on behalf of that individual reside (or resided) in an area for which a Federal, State or local government entity newly declared a disaster or other emergency. The individual (or the individual's authorized representative, legal guardian, or person who makes healthcare decisions on behalf of that individual) must demonstrate that they reside (or resided) in the area during the period covered by that declaration.

(2) *SEP duration.* The SEP begins on the earlier of the date an emergency or disaster is declared or, if different, the start date identified in such declaration. The SEP ends 6 months after the end date identified in the declaration, the end date of any extensions or the date when the declaration has been determined to have ended or has been revoked, if applicable.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(c) *Special enrollment period for individuals affected by a health plan or employer misrepresentation.* An SEP exists for individuals whose non-enrollment in premium Part A is unintentional, inadvertent, or erroneous and results from misrepresentation or reliance on incorrect information provided by the individual's employer or GHP, agents or brokers of health plans, or any person authorized to act on behalf of such entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they can demonstrate (by documentation or written attestation) both of the following:

(i) He or she did not enroll in premium Part A during another enrollment period in which they were eligible based on information received from an employer or GHP, agents or brokers of health plans, or any person authorized to act on such organization's behalf.

(ii) An employer, GHP, agent or broker of a health plan, or their representative materially misrepresented information or provided incorrect information relating to enrollment in premium Part A.

(2) *SEP duration.* This SEP begins the day the individual notifies SSA of the employer or GHP misrepresentation and ends 6 months later.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are released from the custody of penal authorities as described in § 411.4(b) of this subchapter on or after January 1, 2023.

(1) *SEP parameters.* An individual is eligible for this SEP if they demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Medicare premium Part A due to being in custody of penal authorities and there is a record of release either through discharge documents or data available to SSA.

(2) *SEP duration.* The SEP starts the day of the individual's release from the custody of penal authorities and ends the last day of the 12th month after the month in which the individual is released from the custody of penal authorities.

(3) *Entitlement*—(i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(ii) *Special rule.* An individual has the option of requesting entitlement retroactive to the month of their release from incarceration provided the individual pays the monthly premiums for the period of coverage (as required under § 406.31). The retroactive period cannot exceed 6 months.

(e) *Special enrollment period for termination of Medicaid coverage.* An SEP exists for individuals whose Medicaid eligibility is terminated.

(1) *SEP parameters.* An individual is eligible for this SEP if they can demonstrate that—

(i) They are eligible for premium Part A under § 406.5(b); and

(ii) Their Medicaid eligibility is terminated on or after January 1, 2023, or is terminated after the last day of the Coronavirus Disease 2019 public health emergency (COVID–19 PHE) as determined by the Secretary, whichever is earlier.

(2) *SEP duration.* If the termination of Medicaid eligibility occurs—

(i) After the last day of the COVID–19 PHE and before January 1, 2023, the SEP starts on January 1, 2023 and ends on June 30, 2023.

(ii) On or after January 1, 2023, the SEP starts when the individual is notified of termination of Medicaid eligibility and ends 6 months after the termination of eligibility.

(3) *Entitlement*—(i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is after the last day of the COVID–19 PHE or on after January 1, 2023, whichever is earlier.

(ii) *Special COVID–19 PHE rule.* An individual whose Medicaid eligibility is terminated after the end of the COVD–19 PHE, but before January 1, 2023 (if applicable), has the option of requesting

that entitlement begin back to the first of the month following termination of Medicaid eligibility provided the individual pays the monthly premiums for the period of coverage (as required under § 406.31).

(iii) *Other special rule.* After January 1, 2023, an individual has the option of requesting entitlement for a retroactive period back to the date of termination from Medicaid provided the individual pays the monthly premiums for the period of coverage (as required under § 406.31).

(4) *Effect on previously accrued late enrollment penalties.* Individuals who otherwise would be eligible for this SEP, but enrolled during the COVID–19 PHE prior to January 1, 2023, are eligible to have late enrollment penalties collected under § 406.32(d) reimbursed and ongoing penalties removed.

(f) *Special enrollment period for other exceptional conditions.* An SEP exists for other exceptional conditions as CMS may provide.

(1) *SEP parameters.* An individual is eligible for the SEP if both of the following apply:

(i) The individual demonstrates that they missed an enrollment period in which they were eligible because of an event or circumstance outside of the individual's control which prevented them from enrolling in premium Part A.

(ii) It is determined that the conditions were exceptional in nature.

(2) *SEP duration.* The SEP duration is determined on a case-by-case basis, but will be no less than 6 months.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

■ 10. Effective January 1, 2023, § 406.33 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Redesignating paragraph (c) as paragraph (d); and

■ c. Adding new paragraph (c).

The revision and addition read as follows:

§ 406.33 Determination of months to be counted for premium increase: Enrollment.

(a) *Enrollment before April 1, 1981 or after September 30, 1981 and before January 1, 2023.* The months to be counted for premium increase are the months from the end of the initial enrollment period through the end of the general enrollment period, the special enrollment period, or the transfer enrollment period in which the individual enrolls, excluding the following:

* * * * *

(c) *Enrollment on or after January 1, 2023.* The months to be counted for premium increase are the months from the end of the initial enrollment period through the end of the month in which the individual enrolls, excluding both of the following:

(1) The months described in paragraphs (a)(1) through (6) of this section.

(2) Any months of non-coverage in accordance with an individual's use of an exceptional conditions SEP under § 406.27 provided the individual enrolls within the duration of the SEP.

* * * * *

■ 11. Effective January 1, 2023, § 406.34 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Redesignating paragraph (e) as paragraph (f); and

■ c. Adding new paragraph (e).

The revision and addition read as follows:

§ 406.34 Determination of months to be counted for premium increase: Reenrollment.

(a) *First reenrollment before April 1, 1981 or after September 30, 1981 and before January 1, 2023.* The months to be counted for premium increase are:

* * * * *

(e) *Reenrollments on or after January 1, 2023.* (1) The months to be counted for premium increase are as follows:

(i) The months specified in § 406.33(c).

(ii) The months specified in paragraphs (b) and (d) of this section (if applicable).

(iii) The months from the end of the first period of entitlement through the end of the month during the general enrollment period in which the individual reenrolled.

(2) The months excluded from premium increase are the months of non-coverage in accordance with an individual's use of an exceptional conditions SEP under § 406.27, provided the individual enrolls within the duration of the SEP.

* * * * *

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

■ 12. Effective January 1, 2023, the authority citation for part 407 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395p, 1395q, and 1395hh.

■ 13. Effective January 1, 2023, § 407.1 is amended by adding paragraph (a)(6) and revising paragraph (b) to read as follows:

§ 407.1 Basis and scope.

(a) * * *

(6) Sections 1836(b) and 1837(n) of the Act provide for coverage of immunosuppressive drugs as described in section 1861(s)(2)(J) of the Act under Part B beginning on or after January 1, 2023, for eligible individuals whose benefits under Medicare Part A and eligibility to enroll in Part B on the basis of ESRD would otherwise end with the 36th month after the month in which the individual receives a kidney transplant by reason of section 226A(b)(2) of the Act.

(b) *Scope.* This part sets forth the eligibility, enrollment, and entitlement requirements and procedures for the following:

(1) Supplementary medical insurance. (The rules about premiums are in part 408 of this chapter.)

(2) The immunosuppressive drug benefit provided for under sections 1836(b) and 1837(n) of the Act, hereinafter referred to as the Part B-Immunosuppressive Drug Benefit (Part B–ID).

■ 14. Effective January 1, 2023, § 407.11 is revised to read as follows:

§ 407.11 Forms used to apply for enrollment under Medicare Part B.

Forms used to apply for enrollment under the supplementary medical insurance program are available free of charge by mail from CMS, or at any Social Security branch or district office and online at the CMS and SSA websites. As an alternative, the individual may request enrollment by signing a simple statement of request, if he or she is eligible to enroll at that time.

■ 15. Effective January 1, 2023, § 407.23 is added to read as follows:

§ 407.23 Special enrollment periods for exceptional conditions.

(a) *General rule:* Beginning January 1, 2023, in accordance with the Secretary's authority in sections 1837(m) and 1838(g) of the Act, the following SEPs, as defined under § 406.24(a)(4) of this subchapter, are provided for individuals who missed a Medicare enrollment period (as specified in § 407.21, § 407.15 or § 407.20 of this subchapter) due to exceptional conditions as determined by the Secretary and established under paragraphs (b) through (f) of this section. SEPs are provided for exceptional conditions that took place on or after January 1, 2023 except as specified in paragraph (e) of this section.

(b) *Special enrollment period for individuals impacted by an emergency or disaster.* An SEP exists for

individuals prevented from submitting a timely Medicare enrollment request by an emergency or disaster declared by a Federal, State, or local government entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they (or their SSA-authorized representative as defined at 42 CFR 405.910), their legal guardian, or the person who makes healthcare decisions on behalf of that individual, reside (or resided) in an area for which a Federal, State or local government entity newly declared a disaster or other emergency. The individual (or the individual's authorized representative, legal guardian, or the person who makes healthcare decisions on behalf of that individual) must demonstrate that they reside (or resided) in the area during the period covered by that declaration.

(2) *SEP duration.* The SEP begins on the earlier of the date an emergency or disaster is declared or, if different, the start date identified in such declaration. The SEP ends 6 months after the end date identified in the declaration, the end date of any extensions or the date when the declaration has been determined to have ended or has been revoked, if applicable.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(c) *Special enrollment period for individuals affected by a health plan or employer misrepresentation.* An SEP exists for individuals whose non-enrollment in SMI is unintentional, inadvertent, or erroneous and results from misrepresentation or reliance on incorrect information provided by the individual's employer or GHP, agents or brokers of health plans, or any person authorized to act on behalf of such entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they can demonstrate (by documentation or written attestation) the both of the following:

(i) He or she did not enroll in SMI during another enrollment period in which they were eligible based on information received from an employer or GHP, agents or brokers of health plans, or any person authorized to act on such organization's behalf.

(ii) An employer, GHP, agent or broker of a health plan, or their representative materially misrepresented information or provided incorrect information relating to enrollment in SMI.

(2) *SEP duration.* This SEP begins the day the individual notifies SSA of the employer or GHP misrepresentation, or the incorrect information provided and ends 6 months later.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are released from the custody of penal authorities as described in § 411.4(b) of this subchapter on or after January 1, 2023.

(1) *SEP parameters.* An individual is eligible for this SEP if they demonstrate that they are eligible for Medicare and failed to enroll or reenroll in SMI due to being in custody of penal authorities, and there is a record of release either through discharge documents or data available to SSA.

(2) *SEP duration.* The SEP starts the day of the individual's release from the custody of penal authorities and ends the last day of the 12th month after the month in which the individual is released from the custody of penal authorities.

(3) *Entitlement*—(i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on after January 1, 2023.

(ii) *Special rule.* An individual has the option of requesting entitlement for a retroactive period of up to 6 months provided the date does not precede release from incarceration and the individual pays the monthly premiums for the period of coverage (as required under § 406.31). If the application is filed within the first 6 months of the SEP, the effective date is retroactive to the date of their release from incarceration. If the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to 6 months after the date of release from incarceration.

(e) *Special enrollment period for termination of Medicaid coverage.* An SEP exists for individuals whose Medicaid eligibility is terminated.

(1) *SEP parameters.* An individual is eligible for this SEP if they can demonstrate that—

(i) They are eligible for Part B under § 407.4(a); and

(ii) Their Medicaid eligibility is being terminated on or after January 1, 2023, or after the last day of the Coronavirus Disease 2019 public health emergency (COVID–19 PHE) as determined by the Secretary, whichever is earlier.

(2) *SEP duration.* If the termination of Medicaid eligibility occurs—

(i) After the last day of the COVID–19 PHE and before January 1, 2023, the SEP starts on January 1, 2023 and ends on June 30, 2023.

(ii) On or after January 1, 2023, the SEP starts when the individual is notified of termination of Medicaid eligibility and ends 6 months after the termination of eligibility.

(3) *Entitlement*—(i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is the month following the last month of the COVID–19 PHE or on or after January 1, 2023, whichever is earlier.

(ii) *Special COVID–19 PHE rule.* An individual whose Medicaid eligibility is terminated after the end of the COVD–19 PHE, but before January 1, 2023 (if applicable), has the option of requesting that entitlement begin back to the first of the month following termination of Medicaid eligibility provided the individual pays the monthly premiums for the period of coverage (as required under part 408 of this subchapter).

(iii) *Other special rule.* After January 1, 2023, an individual has the option of requesting entitlement for a retroactive period back to the date of termination from Medicaid provided the individual pays the monthly premiums for the period of coverage (as required under § 406.31 of this subchapter).

(4) *Effect on previously accrued late enrollment penalties.* Individuals who otherwise would be eligible for this SEP, but enrolled during the COVID–19 PHE prior to January 1, 2023, are eligible to have late enrollment penalties collected under § 408.22 of this subchapter reimbursed and ongoing penalties removed.

(f) *Special enrollment period for other exceptional conditions.* An SEP exists for other exceptional conditions as CMS may provide.

(1) *SEP parameters.* An individual is eligible for the SEP if both of the following apply:

(i) The individual demonstrates that they missed an enrollment period in which they were eligible because of an event or circumstance outside of the individual's control which prevented them from enrolling in SMI.

(ii) It is determined that the conditions were exceptional in nature.

(2) *SEP duration.* The SEP duration is determined on a case by case basis, but will be no less than 6 months.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

■ 16. Effective January 1, 2023, § 407.25 is amended by revising paragraphs (a) and (b)(1) and (3) to read as follows:

§ 407.25 Beginning of entitlement: Individual enrollment.

* * * * *

(a) *Enrollment during initial enrollment period.* For individuals who first meet the eligibility requirements of § 407.10 in a month beginning—

(1) Before January 1, 2023, the following entitlement dates apply:

(i) If an individual enrolls during the first 3 months of the initial enrollment period, entitlement begins with the first month of eligibility.

(ii) If an individual enrolls during the fourth month of the initial enrollment period, entitlement begins with the following month.

(iii) If an individual enrolls during the fifth month of the initial enrollment period, entitlement begins with the second month after the month of enrollment.

(iv) If an individual enrolls in either of the last 2 months of the initial enrollment period, entitlement begins with the third month after the month of enrollment.

(v) For example, if an individual first meets the eligibility requirements for enrollment in April, then the individual's initial enrollment period is January through July. The month in which the individual enrolls determines the month that begins the period of entitlement, as follows:

TABLE 1 TO PARAGRAPH (a)(1)(v)

Enrolls in initial enrollment period	Entitlement begins on—
January	April 1 (month eligibility requirements first met).
February	April 1.
March	April 1.
April	May 1 (month following month of enrollment).
May	July 1 (second month after month of enrollment).
June	September 1 (third month after month of enrollment).
July	October 1 (third month after month of enrollment).

(2) On or after January 1, 2023, the following entitlement dates apply:

(i) If an individual enrolls during the first 3 months of the initial enrollment period, entitlement begins with the first month of eligibility.

(ii) If an individual enrolls during the last 4 months of the initial enrollment period, entitlement begins with the month following the month in which they enroll.

(b) * * *

(1) If an individual enrolls or reenrolls during a general enrollment period before April 1, 1981, or after September 30, 1981 and before January 1, 2023, entitlement begins on July 1 of that calendar year.

* * * * *

(3) If an individual enrolls or reenrolls during a general enrollment period on or after January 1, 2023, entitlement begins on the first day of the month following the month in which they enroll.

* * * * *

■ 17. Effective January 1, 2023, § 407.40 is amended—

■ a. By ading paragraphs (a)(6) through (10);

■ b. By revising paragraph (b) introductory text;

■ c. In paragraph (b) by—

■ i. Adding a definition for ''1634 State'' in alphanumerical order;

■ ii. Revising the definition of ''AFDC'';

■ iii. Adding a definition for ''Buy-in group'' in alphabetical order;

■ iv. Redesignating the definition of ''Cash assistance'' in alphabetical order;

■ v. Removing the definition of ''Qualified Medicare Beneficiary'';

■ vi. Redesignating the definition of ''Railroad retirement beneficiary'' in alphabetical order; and

■ vii. Revising the definition of ''State buy-in agreement or buy-in agreement'';

■ d. By revising paragraph (c)(1); and

■ e. By adding paragraphs (c)(5) and (6).

The additions and revisions read as follows:

§ 407.40 Enrollment under a State buy-in agreement.

(a) * * *

(6) Section 4501 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) established the Specified Low-Income Medicare Beneficiary or SLMB eligibility group effective January 1993.

(7) Section 4732 of the Balanced Budget Act of 1997 (Pub. L. 105–33) established the Qualifying Individual or QI eligibility group effective January 1998.

(8) Section 112 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) increased the resource standard for QMB, SLMB, and QI to 3 times the maximum resources available under the Supplemental Security Income program, adjusted annually by increases in the Consumer Price Index effective January 1, 2010.

(9) Title II, section 211, of the Medicare Access and CHIP Reauthorization Act (Pub. L. 114–10), effective April 16, 2015, permanently extended the QI eligibility group.

(10) Title II, section 402 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260), effective January 1, 2023, expands QMB, SLMB, and QI to cover individuals who are enrolled in Medicare Part B for coverage of immunosuppressive drugs.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise—

1634 State means a State that has an agreement with SSA, in accordance with section 1634 of the Act, for SSA to determine Medicaid eligibility on behalf of the State for individuals residing in the State whom the SSA has determined eligible for SSI.

* * * * *

AFDC stands for aid to families with dependent children under Part A of title IV of the Act, as it was in effect on July 16, 1996.

* * * * *

Buy-in group means a coverage group described in section 1843 of the Act that is identified by the State and is composed of multiple Medicaid eligibility groups specified in the buy-in agreement.

* * * * *

State buy-in agreement or buy-in agreement means an agreement authorized or modified by section 1843 or 1818(g) of the Act, under which a State secures Part B or premium Part A coverage for individuals who are members of the buy-in group specified in the agreement, by enrolling them and paying the premiums on their behalf. A State's submission of a State plan amendment addressing its buy-in process, if approved by CMS, constitutes the ''buy-in agreement'' between the State and CMS for purposes of sections 1843 and 1818(g) of the Act.

(c) * * *

(1) A State that has a buy-in agreement in effect must enroll any individual who is eligible to enroll in SMI under § 407.10 and who is a member of the buy-in group, with the State paying the premiums on the individual's behalf. Individuals enrolled in the buy-in group can enroll in Part B at any time of the year, without regard to Medicare enrollment periods.

* * * * *

(5) In a 1634 State, CMS enrolls SSI beneficiaries in Medicare Part B, on behalf of the State, with the State paying the beneficiary's Part B premiums.

(6) Premiums paid under a State buy-in agreement are not subject to increase because of late enrollment or reenrollment.

■ 18. Effective January 1, 2023, § 407.42 is revised to read as follows:

§ 407.42 Buy-in groups available to the 50 States, the District of Columbia, and the Northern Mariana Islands.

(a) *Basic rule.* The 50 States, the District of Columbia, and the Northern Mariana Islands must select one of the buy-in groups described in paragraph (b) in their buy-in agreements.

(b) *Buy-in groups available*—(1) *Group 1.* Cash Assistance and Deemed

Recipients of Cash Assistance: This buy-in group includes all of the following:

(i) Individuals who receive SSI or SSP or both and are covered under the State's Medicaid state plan as categorically needy.

(ii) Individuals who under the Act or any other provision of Federal Law are treated, for Medicaid eligibility purposes, as though the individual was receiving SSI or SSP and are covered under the State's Medicaid state plan as categorically needy.

(iii) At State option, individuals whom the State must consider to be recipients of AFDC. Individuals a State would be required to include in electing this option would be, but not limited to, individuals eligible for Medicaid on the basis of section 1931(b) of the Act or their receipt of adoption assistance, foster care or guardianship care under Part E of title IV of the Act, in accordance with § 435.145 of this chapter.

(2) *Group 2.* Cash Assistance and Deemed Recipients of Cash Assistance and three Medicare Savings Program eligibility groups. This buy-in group includes both of the following:

(i) Group 1.

(ii) Individuals enrolled in the—

(A) Qualified Medicare Beneficiary eligibility group described in § 435.123 of this chapter;

(B) Specified Low-Income Beneficiary eligibility group described in § 435.124 of this chapter; and

(C) Qualifying Individual eligibility group described in § 435.125 of this chapter.

(3) *Group 3.* All Medicaid Eligibility Groups: This buy-in group includes all individuals eligible for Medicaid.

§ 407.45 [Removed]

■ 19. Effective January 1, 2023, § 407.45 is removed.

■ 20. Effective January 1, 2023, § 407.47 is amended by revising paragraphs (a)(2) (b), (c) introductory text, and (d) introductory text and adding reserved paragraph (f) and paragraph (g) to read as follows:

§ 407.47 Beginning of coverage under a State buy-in agreement.

(a) * * *

(2) The effective date of the buy-in agreement or agreement modification that covers the buy-in group to which the individual belongs, and which may not be earlier than the third month after the month in which the agreement or modification is executed. The State must apply the earliest applicable start date for the applicable buy-in group.

* * * * *

(b) *Application of general rule: Medicaid eligibles who are, or are treated as, cash assistance beneficiaries.* For Medicaid eligibles who are, or are treated as, cash assistance beneficiaries, coverage begins with the later of the following:

(1) The first month in which the individual—

(i) Meets the SMI eligibility requirements specified in § 407.10; and

(ii) Is, or is treated as, a cash assistance beneficiary.

(2) The month in which the buy-in agreement is effective.

(c) *Application of general rule: Qualified Medicare Beneficiaries.* For individuals who are QMBs as defined under § 435.123 of this chapter, coverage begins with the later of the following:

* * * * *

(d) *Application of general rule: Other individuals eligible for Medicaid.* For individuals who are not cash assistance beneficiaries, are not treated as cash assistance beneficiaries, and are not QMBs, coverage begins with the later of the following:

* * * * *

(f) [Reserved].

(g) *Part B enrollment under a buy-in agreement.* Individuals in a buy-in group can enroll in Part B at any time of the year, without regard to Medicare enrollment periods.

■ 21. Effective January 1, 2024, § 407.47 is further amended by adding paragraph (f) to read as follows:

§ 407.47 Beginning of coverage under a State buy-in agreement.

* * * * *

(f) *Exception to the general rule: Limitations on retroactive adjustments in the case of retroactive Medicare Part A entitlement.* (1) In cases in which a Medicaid beneficiary is retroactively entitled to Medicare Part A, beginning with retroactive determinations made on or after January 1, 2024, State liability for retroactive Medicare Part B premiums for Medicaid beneficiaries under a buy-in agreement is limited to a period of no greater than 36 months prior to the date of the Medicare eligibility determination.

(2) The Secretary may grant good cause exceptions for periods of greater or less than 36 months if application of paragraph (f)(1) of the section would result in harm to a beneficiary or if the State cannot benefit from Medicare and further limiting State liability would not result in harm to the beneficiary.

* * * * *

■ 22. Effective January 1, 2023, § 407.48 is amended by revising paragraphs (c)(1) and (2) and adding paragraph (e) to read as follows:

§ 407.48 Termination of coverage under a State buy-in agreement.

* * * * *

(c) * * *

(1) On the last day of the last month for which he or she is eligible for inclusion in the buy-in group, if CMS determines ineligibility or receives a State ineligibility notice by a processing cut-off date as described in paragraph (e) of this section, by the second month after the month in which the individual becomes ineligible for inclusion in the buy-in group.

(2) On the last day of the second month before the month in which CMS receives a State ineligibility notice later than the time specified in paragraph (c)(1) of this section. If CMS receives a notice after the processing cut-off date conveyed under paragraph (e) of this section, CMS considers it to have been received the following month.

* * * * *

(e) *Processing cut-off dates for each calendar month.* On a quarterly basis, CMS is to prospectively convey to States a schedule of processing cut-off dates for each calendar month.

■ 23. Effective January 1, 2023, add subpart D to read as follows:

Subpart D—Part B Immunosuppressive Drug Benefit

Sec.

Subpart D—Part B Immunosuppressive Drug Benefit

§ 407.55 Eligibility to enroll.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, an individual is eligible to enroll, be deemed enrolled, or reenroll in the Part B–ID benefit if their Part A entitlement ends as described in § 406.13(f)(2) of this subchapter.

(b) *Exception.* An individual is not eligible for the Part B–ID benefit if the individual is enrolled in or for any of the following:

(1) A group health plan or group or individual health insurance coverage, as such terms are defined in section 2791 of the Public Health Service Act.

(2) Coverage under the TRICARE for Life program under section 1086(d) of title 10, United States Code.

(3) A State plan (or waiver of such plan) under title XIX and is eligible to receive benefits for immunosuppressive drugs described in section 1836(b) of the Act under such plan (or such waiver).

(4) A State child health plan (or waiver of such plan) under title XXI and is eligible to receive benefits for such drugs under such plan (or such waiver).

(5) The patient enrollment system of the Department of Veterans Affairs established and operated under section 1705 of title 38, United States Code and is either of the following:

(i) Not required to enroll under section 1705 of title 38 to receive immunosuppressive drugs described in section 1836(b) of the Act.

(ii) Otherwise eligible under a provision of title 38, United States Code, other than section 1710 of such title, to receive immunosuppressive drugs described in section 1836(b) of the Act.

(c) *Appeals.* Denials for enrollment in the Part B–ID benefit will be considered an initial determination that is appealable under § 405.904(a)(1) of this subchapter.

§ 407.57 Part B–ID benefit enrollment.

(a) *Deemed enrollment.* An individual whose Part A entitlement ends in accordance with § 406.13(f)(2) of this subchapter on or after January 1, 2023, is deemed to have enrolled into the Part B–ID benefit effective the first day of the month in which the individual first satisfies § 407.55, provided he or she provides the attestation required under § 407.59 prior to the termination of their Part A benefits.

(b) *Individual enrollment.* An individual whose Part A entitlement ends in accordance with § 406.13(f)(2) of this subchapter, and who meets the requirements of § 407.55 and provides the attestation required under § 407.59, may enroll in the Part B–ID benefit under the following conditions:

(1) If the individual's entitlement ends prior to January 1, 2023, he or she may enroll in the Part B–ID benefit beginning on October 1, 2022.

(2) If individual's entitlement ends on or after January 1, 2023, the individual may enroll at any time after their entitlement ends.

(c) *Reenrollment.* An individual who had previously enrolled in the Part B–ID benefit, but terminated that benefit, can reenroll at any time, provided the individual meets the requirements of § 407.55 and provides the attestation required under § 407.59.

(d) *Attestation.* To enroll in the Part B–ID benefit, an individual must submit the required attestation as described in § 407.59.

(e) *Entitlement date.* The entitlement to the Part B–ID benefit will start as follows:

(1) For enrollments provided under paragraph (a) of this section, entitlement is effective the month Part A benefits are terminated.

(2) For enrollments provided under paragraphs (b) and (c) of this section, the Part B–ID benefit is effective the month following the month in which the individual provides the attestation required in § 407.59.

(3) *Exception.* Enrollments submitted October 1, 2022 through December 31, 2022, are effective January 1, 2023.

§ 407.59 Attestation.

As a condition of enrollment, an individual must attest to SSA in either a verbal attestation, signed paper form provided by SSA, by electronic submission, or fax, using procedures determined by SSA, that—

(a) The individual is not enrolled and does not expect to enroll in other coverage described in § 407.55(b); and

(b) If the individual does enroll in other coverage described in § 407.55(b), the individual will notify SSA within 60 days of enrollment in such other coverage.

§ 407.62 Termination of coverage.

(a) *Other coverage.* An individual who enrolls in other coverage as described in § 407.55(b) will have his or her enrollment in the Part B–ID benefit terminated on either of the following bases:

(1) If the individual notifies SSA of such coverage consistent with § 407.59(b), their enrollment in the Part B–ID benefit will be terminated effective the first day of the month after the month of notification unless the individual requests a different, prospective termination date that is not after the effective date of enrollment in other health insurance coverage, as described in § 407.55(b).

(2) If the individual does not notify SSA of this coverage consistent with § 407.59(b), their enrollment in the Part B–ID benefit will be terminated effective the first day of the month after the month in which there is a determination of the individual's enrollment in coverage described in § 407.55(b).

(b) *Death.* Enrollment in the Part B–ID benefit ends on the last day of the month in which the individual dies.

(c) *Nonpayment of premiums.* If an individual fails to pay the premiums, the Part B–ID benefit enrollment will end as provided in the rules for Part B premiums set forth in part 408 of this chapter.

(d) *Request by individual.* An individual may request disenrollment at any time by notifying SSA that he or she no longer wants to be enrolled in the Part B–ID benefit. Such individual's enrollment in the Part B–ID benefit ends with the last day of the month in which the individual provides the disenrollment request, except for an individual who loses coverage under a State buy-in agreement, as described in § 407.50(b)(2)(i).

(e) *Entitlement to Hospital Insurance benefits.* Enrollment in the Part B–ID benefit ends effective the last day of the month prior to the month that the individual becomes entitled to benefits under § 406.5, § 406.12, or § 406.13 of this subchapter.

(f) *Appeals.* An involuntary termination of the Part B–ID benefit for reasons described at § 407.62(a)(2), (b), or (c) of this subsection, will be considered an initial determination that is appealable under § 405.904(a)(1) of this subchapter. An individual can request to continue receiving Part B–ID benefits while waiting for an appeals decision.

PART 408—PREMIUMS FOR SUPPLEMENTARY MEDICAL INSURANCE

■ 24. Effective January 1, 2023, the authority citation for part 408 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 25. Effective January 1, 2023, § 408.20 is amended by adding paragraph (f) to read as follows:

§ 408.20 Monthly premiums.

* * * * *

(f) *Part B–ID premiums*—(1) *Premium amount.* Beginning in 2022, and every year thereafter, the Secretary, as mandated by section 1839(j) of the Act, will determine and promulgate a monthly premium rate in September for the succeeding calendar year for individuals enrolled only in the Part B–ID benefit. Such premium is equal to 15 percent of the monthly actuarial rate for enrollees age 65 and over for that succeeding calendar year.

(2) *Premium adjustments.* (i) The Part B–ID benefit premium is subject to adjustments specified in §§ 408.20(e), 408.27, and 408.28.

(ii) The Part B–ID benefit premium is not subject to § 408.22.

(3) *Premium collection.* Premiums for the Part B–ID benefit are collected as set out in § 408.6 and subpart C of this part.

(4) *Premium deductions.* Part B–ID premiums are to be deducted following the rules set forth in § 408.40.

■ 26. Effective January 1, 2023, § 408.24 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Redesignating paragraph (b) as paragraph (c);

■ c. Adding new paragraph (b);
■ d. Revising newly redesignated paragraph (c) introductory text; and
■ d. Adding paragraph (d).

The revisions and additions read as follows:

§ 408.24 Individuals who enrolled or reenrolled before April 1, 1981 or after September 30, 1981.

(a) *Enrollment.* For an individual who first enrolled before April 1, 1981 or after September 30, 1981 and before January 1, 2023, the period includes the number of months elapsed between the close of the individual's initial enrollment period and the close of the enrollment period in which he or she first enrolled, and excludes the following:

* * * * *

(b) *Enrollment on or after January 1, 2023.* For an individual who first enrolled on or after January 1, 2023, the period *includes* the number of months elapsed between the close of the individual's initial enrollment period and the close of the month in which he or she first enrolled and *excludes*—

(1) The periods of time described in (a)(1) through (10) of this section; and

(2) Any months of non-coverage in accordance with an individual's use of an exceptional conditions SEP under § 407.23 of this subchapter provided the individual enrolls within the duration of the SEP.

(c) *Reenrollment.* For an individual who reenrolled before April 1, 1981, or after September 30, 1981, and before January 1, 2023, the period—

* * * * *

(d) *Reenrollment on or after January 1, 2023.* For an individual who reenrolled on or after January 1, 2023, the period—

(1) Includes the number of months specified in paragraphs (c)(1)(i) through (iii) of this section; and

(2) Excludes—

(i) The number of months specified in paragraphs (c)(2)(i) and (ii) of this section; and

(ii) Any months of non-coverage in accordance with an individual's use of an exceptional conditions SEP under § 407.23 of this subchapter provided the individual enrolls within the duration of the SEP.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 27. Effective January 1, 2023, the authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 28. Effective January 1, 2023, § 410.30 is amended by revising paragraph (b) to read as follows:

§ 410.30 Prescription drugs used in immunosuppressive therapy.

* * * * *

(b) *Eligibility.* For drugs furnished on or after December 21, 2000, coverage is available only for prescription drugs used in immunosuppressive therapy, furnished to an individual who received an organ or tissue transplant for which Medicare payment is made, provided the individual is eligible to receive Medicare Part B benefits, including, beginning January 1, 2023, an individual who meets the requirements specified in § 407.55 of this subchapter.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 29. Effective January 1, 2023, the authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 30. Effective January 1, 2023, § 423.30 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 423.30 Eligibility and enrollment.

(a) * * *

(1) * * *

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B (but not including an individual enrolled solely for coverage of immunosuppressive drugs under § 407.1(a)(6)) of this subchapter.

* * * * *

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 31. Effective January 1, 2023, the authority citation for part 431 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 32. Effective January 1, 2023, § 431.625 is amended—
■ a. In paragraph (d)(1) by removing the reference ''title I, IV–A, X'' and adding is its place the reference ''title I, X'';
■ b. By removing paragraphs (d)(2)(i), (vi), and (x);
■ c. By redesignating paragraphs (d)(2)(ii) through (v) as paragraphs (d)(2)(i) through (iv), respectively, and redesignating paragraphs (d)(2)(vii) through (ix) as paragraphs (d)(2)(v) through (vii), respectively;
■ d. In newly redesignated paragraph (d)(2)(i) by removing the reference ''435.114,'';
■ e. By revising newly redesignated paragraph (d)(2)(iii);
■ f. In newly redesignated paragraph (d)(2)(iv) by removing ''chapter'' and adding in its place ''subchapter'';
■ g. By revising newly redesignated paragraphs (d)(2)(vi) and (vii);
■ h. By adding new paragraphs (d)(2)(viii) and (ix); and
■ i. In paragraph (d)(3) by removing the reference ''435.914'' and adding in its place the reference ''435.915.''

The revisions additions read as follows:

§ 431.625 Coordination of Medicaid with Medicare Part B.

* * * * *

(d) * * *

(2) * * *

(iii) Beneficiaries whom States must consider to be recipients of AFDC, including those who receive adoption assistance, foster care or guardianship care, under part E of title IV of the Act, in accordance with §§ 435.145 and 436.114(e) of this subchapter, or who receive Medicaid coverage for low income families, in accordance with section 1931(b) of the Act.

* * * * *

(vi) Disabled children living at home to whom the State provides Medicaid under § 435.225 of this subchapter.

(vii) Beneficiaries required to be covered under §§ 435.115 and 436.114(f) and (h) of this subchapter, that is, those who remain eligible for 4 months of temporary Medicaid coverage because of the increased collection of spousal support under part D of title IV of the Act.

(viii) Individuals required to be covered under the QMB, SLMB, and QI eligibility groups, each separately defined in §§ 435.123 through 435.125 of this subchapter.

(ix) Adult children with disabilities, as described in 1634(c) of the Act.

* * * * *

PART 435—MANDATORY COVERAGE OF THE AGED, BLIND AND DISABLED

■ 33. Effective January 1, 2023, the authority citation for part 435 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 34. Effective January 1, 2023, § 435.4 is amended by adding a definition for ''Medicare Savings Programs'' as follows:

§ 435.4 Definitions and use of terms.

* * * * *

Medicare Savings Programs means four Medicaid eligibility groups authorized under section 1902(a)(10)(E) and 1905(p) and (s) of the Act that serve certain low-income Medicare

beneficiaries. These groups include the Qualified Medicare Beneficiary, Specified Low-Income Medicare Beneficiary, Qualifying Individual, and Qualified Disabled and Working Individual eligibility groups, each separately codified in §§ 435.123 through 435.126.

* * * * *

■ 35. Effective January 1, 2023, § 435.123 is added to read as follows:

§ 435.123 Individuals eligible as qualified Medicare beneficiaries.

(a) *Basis.* This section implements sections 1902(a)(10)(E)(i) and 1905(p)(1) of the Act.

(b) *Eligibility.* The agency must provide medical assistance to individuals who meet all of the following:

(1) Are entitled to Medicare Part A based on the eligibility requirements set forth in § 406.5(a) or § 406.20(b) of this chapter or who are enrolled in Medicare Part B for coverage of immunosuppressive drugs based on eligibility requirements described in § 407.55 of this chapter.

(2) Have an income, subject to paragraphs (b)(2)(i) and (ii) of this section, that does not exceed 100 percent of the Federal poverty level.

(i) During a transition month (as defined in paragraph (b)(2)(ii) of this section), any income attributable to a cost of living adjustment in Social Security retirement, survivors, or disability benefits does not count in determining an individual's income.

(ii) A transition month is any month of the year beginning when the cost of living adjustment takes effect, through the month following the month of publication of the revised official poverty level.

(3) Have resources, determined using financial methodologies no more restrictive than SSI, that do not exceed three times the maximum resource level allowed under the SSI program, annually adjusted by increases in the Consumer Price Index for inflation as defined in section 1905(p)(1)(C) of the Act.

(c) *Scope.* Medical assistance included in paragraph (b) of this section includes all of the following:

(1) For individuals entitled to Medicare Part A as described in paragraph (b)(1) of this section, coverage for Parts A and B premiums and cost sharing, including deductibles and coinsurance, and copays.

(2) For individuals enrolled in Medicare Part B for coverage of immunosuppressive drugs as described in paragraph (b)(1) of this section, only coverage of premiums and cost sharing related to enrollment in Medicare Part B for coverage of immunosuppressive drugs.

■ 36. Effective January 1, 2023, § 435.124 is added to read as follows:

§ 435.124 Individuals eligible as specified low-income Medicare beneficiaries.

(a) *Basis.* This section implements sections 1902(a)(10)(E)(iii) and 1905(p)(3)(A)(ii) of the Act.

(b) *Eligibility.* The agency must provide medical assistance to individuals who meet the eligibility requirements in § 435.123(b), except that income exceeds 100 percent, but is less than 120 percent of the poverty level.

(c) *Scope.* Medical assistance included in paragraph (b) of this section includes the following:

(1) For individuals entitled to Medicare Part A as described in paragraph (b)(1) of this section, coverage for the Part B premium.

(2) For individuals enrolled under Medicare Part B for coverage of immunosuppressive drugs as described in paragraph (b)(1) of this section, only coverage of the Part B premium related to enrollment in Medicare Part B for coverage of immunosuppressive drugs.

■ 37. Effective January 1, 2023, § 435.125 is added to read as follows:

§ 435.125 Individuals eligible as qualifying individuals.

(a) *Basis.* This section implements sections 1902(a)(10)(E)(iv) and 1905(p)(3)(A)(ii) of the Act.

(b) *Eligibility.* The agency must provide medical assistance to individuals who meet the eligibility requirements in § 435.123(b), except that income is at least 120 percent, but is less than 135 percent of the Federal poverty level.

(c) *Scope.* Medical assistance included in paragraph (b) of this section includes the following:

(1) For individuals entitled to Medicare Part A as described in paragraph (b)(1) of this section, coverage for the Part B premium.

(2) For individuals enrolled under Medicare Part B for coverage of immunosuppressive drugs as described in paragraph (b)(1) of this section, only payment of the Part B premium related to enrollment in Medicare Part B for coverage of immunosuppressive drugs.

■ 38. Effective January 1, 2023, § 435.126 is added to read as follows:

§ 435.126 Individuals eligible as Qualified Disabled and Working Individuals.

(a) *Basis.* This section implements sections 1902(a)(10)(E)(ii) and 1905(s) of the Act.

(b) *Eligibility.* The agency must provide medical assistance to individuals who meet all of the following:

(1) Are entitled to Medicare Part A based on the eligibility requirements set forth in § 406.20(c) of this chapter.

(2) Have income, subject to paragraphs (b)(2)(1)(i) and (ii) of this section, that is less than or equal to 200 percent of the federal poverty level.

(i) During a transition month (as defined in paragraph (b)(2)(ii) of this section), any income attributable to a cost of living adjustment in Social Security retirement, survivors, or disability benefits does not count in determining an individual's income.

(ii) A transition month is any month of the year beginning when the cost of living adjustment takes effect, through the month following the month of publication of the revised official poverty level.

(3) Have resources that do not exceed twice the SSI resource standard described in section 1613 of the Act.

(c) *Scope.* Medical assistance included in paragraph (b) of this section is coverage of the Part A premium.

Dated: October 24, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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