



FEDERAL REGISTER

Vol. 77

Friday,

No. 82

April 27, 2012

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 424 and 431

Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 424 and 431

[CMS–6010–F]

RIN 0938–AQ01

Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule finalizes several provisions of the Affordable Care Act implemented in the May 5, 2010 interim final rule with comment period. It requires all providers of medical or other items or services and suppliers that qualify for a National Provider Identifier (NPI) to include their NPI on all applications to enroll in the Medicare and Medicaid programs and on all claims for payment submitted under the Medicare and Medicaid programs. In addition, it requires physicians and other professionals who are permitted to order and certify covered items and services for Medicare beneficiaries to be enrolled in Medicare. Finally, it mandates document retention and provision requirements on providers and supplier that order and certify items and services for Medicare beneficiaries.

DATES: Effective June 26, 2012 the interim final rule amending 42 CFR parts 424 and 431 that published on May 5, 2010 (75 FR 24437) is confirmed as final with changes.

FOR FURTHER INFORMATION CONTACT:

Katie Mucklow Lehman, (410) 786–0537, for Medicare issues.

Donna Schmidt, (410) 786–5532 for Medicaid issues.

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare program, title XVIII of the Social Security Act (the Act), is the primary payer of health care for approximately 50 million beneficiaries. Under section 1802 of the Act, a beneficiary may obtain health services from an individual or organization qualified to participate in the Medicare program.

Providers and suppliers furnishing services must comply with the Medicare requirements stipulated in the Act and in implementing regulations. These

requirements are meant to promote the furnishing of quality care, while protecting the integrity of the program. As Medicare program expenditures have grown, the Centers for Medicare & Medicaid Services (CMS) has increased its efforts to ensure that only qualified individuals or organizations are allowed to enroll in Medicare and maintain Medicare billing privileges.

The Medicaid program, established under title XIX of the Act pays for medical benefits to tens of millions of people. Medicaid is a joint Federal and State health care program for eligible low-income individuals. The Medicaid program works within a broad Federal framework and States have considerable flexibility in how the program is administered.

The Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act) makes many changes to the Medicare and Medicaid programs, some of which involve strengthening tools for quality and integrity. To maintain program integrity and ensure quality, we must make certain that only qualified providers and suppliers participate in the programs and that they bill accurately for their services. With respect to Medicaid, our regulations provide States with considerable flexibility. However, the Federal framework includes some key requirements to ensure program integrity while providing quality care. For example, Medicaid providers must generally meet all State licensing and scope-of-practice requirements, and may be subject to additional Federal and State quality standards. Additionally, the Medicare and Medicaid regulations require timely filing of claims by providers.

In the May 5, 2010 *Federal Register* (75 FR 24437), we published an interim final rule with comment period (IFC) that implemented several provisions of the Affordable Care Act regarding provider and supplier enrollment, ordering and referring; documentation requirements, and changes in provider agreements.

II. Provisions of the Interim Final Rule With Comment Period and Summary of Responses to Comments

In this section of the final rule, we provide the following for each of the provisions of the May 5, 2010 IFC:

- Background.
- Statutory changes based on the Affordable Care Act.
- The provisions of the IFC.

- Summary of the comments and responses to the public comments received on the IFC. We received approximately 224 timely comments on the May 5, 2010 IFC.

With regard to the Medicare provisions, we also note that the term “provider,” as used throughout the IFC and in this final rule, has the meaning specified in § 400.202.

For Medicaid, the term “provider,” as used throughout the IFC and in this final rule, has the meaning specified in § 400.203. That is, for purposes of this rule provider means any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.

We also note that the use of the term “supplier,” in the IFC and in this final rule, as defined at § 400.202, with regard to the Medicare provisions, is “a physician or other practitioner, or an entity other than a provider that furnishes health care services under Medicare.” In portions of this final rule, the commenters and CMS may only use the term “provider(s)” or “supplier(s).” However, the reader should consider these terms as relating to both providers and suppliers, unless explicitly stated otherwise. The regulatory text, however, uses precise language.

Finally, throughout this final rule, we have attempted to remain consistent with our terminology regarding the term “resident.” We draw the reader’s attention to § 413.75(b) where a resident is defined as “* * * an intern, resident, or fellow who participates in an approved medical residency program, including programs in osteopathy, dentistry, and podiatry, as required in order to become certified by the appropriate specialty board.” We want to be explicit in stating that the term “resident” incorporates interns, residents, and fellows and we will use this term to refer to all three professionals throughout this final rule.

A. Inclusion of the National Provider Identifier (NPI) on All Medicare and Medicaid Enrollment Applications and Claims

1. Background

Historically, we have identified vulnerabilities in Medicare enrollment procedures that have permitted the enrollment of providers and suppliers whose qualifications for meeting all of our enrollment standards were sometimes questionable. This raised concerns that certain providers and suppliers in our program may be under-qualified or even fraudulent and has led us to increase our efforts to establish more stringent controls on provider and

supplier entry into the Medicare program. These efforts include the publication of the following rules:

- A final rule with comment titled, “Additional Supplier Standards” (October 11, 2000, 65 FR 60366).
- A final rule titled, “Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment” (April 21, 2006, 71 FR 20754).
- A final rule titled, “Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007” (December 1, 2006, 71 FR 69624).
- A final rule titled, “Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)” (April 10, 2007, 72 FR 17992).
- A final rule titled, “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Final Rule” (72 FR 66222).
- A final rule titled, “Appeals of CMS or CMS Contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges” (June 27, 2008, 73 FR 36448).
- A final rule with comment titled, “Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)” (November 19, 2008, 73 FR 69726).
- A final rule titled, “Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Final Rule” (January 2, 2009, 74 FR 166).
- A final rule titled, “The National Provider Identifier Rule” (January 23, 2004, 69 FR 3434).
- A final rule titled “Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria,

Payment Suspensions and Compliance Plans for Providers and Suppliers” (February 2, 2011, 76 FR 5862).

The NPI provisions of this final rule are an extension of the aforementioned program integrity initiatives, consistent with the direction of the Affordable Care Act as described later in this section, designed to ensure that only legitimate providers and suppliers that meet and maintain our standards can be enrolled and/or paid by the Medicare program.

Similarly, consistent with the NPI final rule and subsequent guidance from the Secretary, beginning May 23, 2008, Medicaid providers have also been required to report their NPIs on their Medicaid claims.

2. Provisions of the Affordable Care Act

Section 6402(a) of the Affordable Care Act added a new section 1128J of the Act, titled “Medicare and Medicaid Program Integrity Provisions.” Section 1128J(e) of the Act requires the Secretary to promulgate a regulation that requires, not later than January 1, 2011, all providers of medical or other items or services and suppliers under the programs under titles XVIII and XIX that qualify for an NPI to include their NPI on all applications to enroll in such programs and on all claims for payment submitted under such programs. In Medicaid, there is no Federally required “enrollment application,” although all Medicaid providers are required to enter into a provider agreement with the State as a condition of participating in the program under section 1902(a)(27) of the Act. Therefore, in the Medicaid context we are including the submission of an NPI to the State agency as a requirement under the provider agreement. The NPI requirements in this final rule are thus applicable to the reporting of NPIs—(1) pursuant to Medicaid provider agreements; (2) for inclusion in Medicare enrollment records; and (3) on Medicare and Medicaid claims.

3. Requirements Established by the IFC

a. NPI and the Medicare Program

(1) NPI and the Medicare Program Requirements Established by IFC

For the Medicare program, we established the following:

- At § 424.506(a), the definition of “eligible professional” refers to any of the professionals specified in section 1848(k)(3)(b) of the Act.
- At § 424.506(b), requirements that a provider or supplier who is eligible for an NPI must report the NPI on the Medicare enrollment application; and, if the provider or supplier enrolled in Medicare prior to obtaining an NPI and

the NPI is not in the provider’s or supplier’s enrollment record, the provider or supplier must report the NPI to Medicare in an enrollment application so that the NPI will be added to the provider’s or supplier’s enrollment record in PECOS.

- At § 424.506(c)(1), a requirement that a provider or supplier who is enrolled in fee-for-service (FFS) Medicare report its NPI, as well as the NPI of any other provider or supplier who is required to be identified in those claims, on any electronic or paper claims that the provider or supplier submits to Medicare.

- At § 424.506(c)(2) that a claim submitted by a Medicare beneficiary contain the legal name and, if the beneficiary knows the NPI, the NPI of any provider or supplier who is required to be identified in that claim. If a Medicare beneficiary does not know the NPI of a provider or supplier who is required to be identified in the claim that he or she is submitting, the beneficiary may submit the claim without the NPI(s) as long as the claim contains the legal name(s) of the health care provider(s). If a beneficiary so desires, he or she can obtain a provider’s or a supplier’s NPI by requesting it directly from the provider or supplier or from a member of his or her office staff, or by looking it up in the NPI Registry at <https://nppes.cms.gov/NPPES/NPIRegistryHome.do>.

- At § 424.506(c)(3), a Medicare claim from a provider or a supplier will be rejected if it does not contain the required NPI(s).

(2) Summary of and Responses to the IFC Comments Regarding the NPI and the Medicare Program

(a) Effective/Implementation Date

Comment: A commenter noted that the preamble states that the NPI requirements set forth in the IFC, referencing section 6402(a) of the Affordable Care Act, requires the Secretary to promulgate a regulation to implement the NPI requirement no later than January 2011. Therefore, there is confusion as to why July 6, 2010 is the effective date for NPI requirements.

Response: Section 6402(a) of the Affordable Care Act requires the Secretary to promulgate rules implementing the NPI requirement no later than January 2011. However, we have had existing regulations since 2008, as mentioned in the IFC, requiring the use of NPIs on all enrollment applications and claims forms, if NPIs were assigned to the provider. The NPI requirements set forth in the IFC are necessary to implement the data

reporting requirements in section 1128J(e) of the Act, as added by section 6402(a) of the Affordable Care Act, which require that the Secretary promulgate a regulation to implement this requirement no later than January 2011. Moreover these NPI requirements are needed to implement the Medicare ordering and certifying requirements specified in section 6405 of the Affordable Care Act (discussed in section II.B.2. of this final rule) that are effective July 1, 2010. Section 6406 of the Affordable Care Act (discussed in section II.B.4.a. of this final rule) was effective January 1, 2010. It was imperative that the NPI regulatory provisions be set forth as soon as possible to deliver the guidance necessary to enact the document retention provisions. For this reason, the NPI requirement was included in the IFC published on May 5, 2010, with an effective date of July 6, 2010.

(b) Deactivation

Comment: A commenter suggested that CMS permit the use of Electronic File Interface (EFI), which is used for submitting NPI applications to the National Plan and Provider Enumeration System (NPPES), to reactivate Medicare Provider Transaction Access Numbers (PTANs) that have been deactivated for non-billing for 12 consecutive months. This would reduce the burden on physicians and other providers and suppliers who must submit enrollment applications to re-enroll in Medicare if they have been deactivated due to non-billing.

Response: We appreciate the commenter's concerns and desire to use a fully electronic mechanism for reenrollment after deactivation. Currently, all enrollees must sign their paper enrollment application or the Certification Statement for their Internet-based PECOS application. We continue to work with our Medicare contractors to reduce the delays in the enrollment process. We believe these measures will alleviate the concerns of the commenter.

After review of the public comments received, we are retaining the provisions regarding the NPI for the Medicare program with the modification specified in this section and in section III. of this final rule.

To clarify, it is not necessary for the providers and suppliers to fill out an entire enrollment application simply to provide an NPI, we have revised the language in existing § 424.506(b)(2), which has been redesignated as § 424.506(b)(1)(ii), to specify that providers and suppliers that are eligible for an NPI must update their enrollment

records with this information. NPIs must be provided to the Medicare contractors by using a CMS-855 paper form or through Internet-based PECOS.

After consideration of the comments, we are finalizing our policy as it relates to the NPI and the Medicare definitions, enrollment, and claims reporting with a few modifications. We made some technical changes to the language by redesignating and revising language, specifically in § 424.506(b). Section 424.506(b)(3) was redesignated as § 424.506(b)(2) and revised to clarify that opt-out physicians and nonphysician practitioners will not be required to submit an enrollment application for any reason, including to order and certify. We also revised § 424.506(c)(1) to specifically address and clarify the NPIs that were required on the claims.

b. NPI and the Medicaid Program

(1) NPI Requirements for the Medicaid Program Established by IFC

Consistent with the requirements of section 6402(a) of the Affordable Care Act, we added a new (b)(5)(i) and (ii) to § 431.107 to require that the provider agreement between a State agency and each provider delivering services under the State plan include a requirement that the provider furnish to the State agency its NPI (if eligible for an NPI); and include its NPI on all claims submitted under the Medicaid program. In Medicaid, under section 1902(a)(77) of the Act, States are required to comply with the provider screening, oversight, and reporting requirements outlined in section 1902(kk) of the Act including the process for screening providers established under section 1866(j) of the Act. In addition, there are new Federal regulatory requirements for provider enrollment and screening, published in the February 2, 2011 **Federal Register** (76 FR 5862). The requirements under section 1902(a)(77) of the Act and under these new Federal regulatory requirements for provider enrollment and screening provide guidance for certain aspects of provider enrollment but do not provide Federal requirements for the entire process. However, providers are required to enter into a provider agreement with the State as a condition of participating in the program under section 1902(a)(27) of the Act. For purposes of the IFC, we interpreted the Affordable Care Act's reference to "applications to enroll" to refer to provider agreements in the Medicaid context. Additionally, we required that the NPI be submitted on all claims for payment to the Medicaid program on and after July 6, 2010.

(2) Summary of and Responses to the Public Comments Related to the NPI and the Medicaid Program

Comment: A commenter requested clarification regarding NPIs on pharmacy claims specifically when a pharmacy submits a prescriber Drug Enforcement Administration (DEA) number or State license number in lieu of the NPI. Is it expected that the pharmacy and physician NPIs are submitted on the claim for payment? Should the claims processor reject the claim if one or both provider identification numbers are not NPIs?

Response: The statute and this regulation require that NPIs be included on all claims for payment for Medicaid, including pharmacy claims. The requirement for an NPI does not replace the function of the DEA number, which must appear on all prescriptions for scheduled drugs, or the State license number, which is issued by an applicable State licensing authority; however, these numbers have different purposes and are not to be used to identify the prescriber when billing a claim at point of sale. The NPI was adopted to identify a health care provider as a health care provider in standard transactions adopted under the HIPAA. Effective July 6, 2010, NPI numbers are required on pharmacy claims.

Comment: A commenter stated that if pharmacy claims must include the NPI of the prescriber, the July 6, 2010 date will be impossible to meet due to the systems changes that would need to be made. The commenter believed that the date of January 1, 2011, which is the date in the Affordable Care Act, would be a more realistic compliance date.

Response: We believe the commenter is inquiring about the requirement that the NPI of the ordering or referring provider be included on all Medicaid claims for payment. This requirement was finalized in a February 2, 2011 final rule (76 FR 5862) and was effective March 25, 2011. Thus, this comment is outside the scope of this final rule, which, for purposes of Medicaid, only requires that the NPI of the provider furnishing the services/submitting the claim (for example, the pharmacy) be included on the claim.

Comment: A commenter requested clarification on the process for physician assistants (PAs) under different State Medicaid programs. PAs qualify for NPIs and are providers of medical services in some State Medicaid programs. However, not all States enroll PAs and in some States, the PA's NPI is not included on the claim form. Will this rule mean a change in policy and

procedure and that all States will now be required to include the PA's NPI on claims?

Response: If a PA is independently licensed to practice in a State and that State has included PAs as a provider type under the Medicaid State plan, the NPI number for that PA is required to be included on all claims for payment and pursuant to the PA's provider agreement. If the PA is not independently licensed within the State but rather is under the supervision of the physician, and/or is not described as a provider type that bills for Medicaid services under the State Plan, the NPI of the PA is irrelevant since the PA is not directly billing Medicaid; however, the supervising physician must have an NPI on submitted claims for payment and pursuant to the provider agreement.

Comment: Commenters expressed concern that adding and using NPI numbers on claims could result in burdensome investigations or liability for dentists in cases where their NPI numbers could be used fraudulently or criminally. These commenters requested procedures to protect practitioners from any unreasonable additional compliance burden that may be incident to the misuse of their NPIs by others.

Other commenters acknowledged that the NPI registry permits anyone with a computer and internet access to look up a provider's NPI by name. The commenters inquired how CMS is able to determine whether the NPI that is on a claim was put there by a physician who meant to order the test, or by someone who simply downloaded the NPI from the open file, thereby identifying attempts at theft and fraud?

Response: Under Medicaid, a claim submitted for payment that does not include the provider's NPI will be denied. In cases where claims submitted for payment do include an NPI number, the State's Medicaid Management Information System will match NPI numbers for providers with other data included in the State's provider enrollment file to ensure the provider's identity. This cross-checking with other data within the State ensures that the NPI number is valid and that it matches with all data in the provider enrollment file in an effort to verify each provider's identity. Additionally, this cross-checking is done at the State level and does not impose any additional compliance burdens on providers.

Comment: A commenter requested clarification regarding whether States need only to collect NPIs through the usual annual agreements and no additional actions for physicians will be required this year to report NPIs.

Response: NPIs must be added pursuant to provider agreements for new providers effective July 6, 2010. Existing providers must submit their NPIs pursuant to their provider agreements at the time in which they are revalidated or at the time in which changes are made to existing provider agreements. The NPI for all providers in Medicaid must be included on all claims submitted for payment effective July 6, 2010. We wish to note that since provider NPIs must be submitted on all claims for payment under Medicaid effective July 6, 2010, it may make sense for all providers (new and existing) to consider adding NPIs pursuant to provider agreements at the time in which they also submit a claim for payment.

Comment: A commenter questioned patient access and home health agencies' requests for payments for dual Medicaid/Medicare patients in the following scenario—a patient has been admitted to Medicaid Home Health after meeting the Medicaid homebound criteria, but not Medicare homebound criteria at the level of receiving skilled nursing care (for example wound care). The patient regresses, and now meets Medicare homebound criteria. A new Medicare Start of Care begins, and claims can be submitted to Medicare. What would the process be if this patient's physician is not enrolled in PECOS?

Response: Under the Medicaid program, the provider is required to include an NPI number on all claims for payment and pursuant to the provider agreement with the State. If the home health agency submits a claim to Medicare for home health services and the certifying physician is not enrolled in Medicare or has not validly opted-out, as required by the provisions of this rule, the claim will be denied by Medicare once the automated edits are activated.

After consideration of the comments, we are finalizing our policy as it relates to the NPI and Medicaid claims; that is, the effective date for the inclusion of the NPI on all Medicaid claims for payment remains July 6, 2010. The effective date for submission of NPIs pursuant to provider agreements for new providers also remains July 6, 2010. However, we are revising our policy as it relates to the NPI pursuant to provider agreements for existing providers; that is, the effective date for inclusion of the submission of NPIs pursuant to provider agreements for existing providers will be upon the next date that a change must be made to the provider agreement or upon the date of revalidation. This policy revision does not impact the regulatory

text (§ 431.107(b)(5)) as specified in the IFC (75 FR 24437). Therefore, we are not amending the regulatory text in this final rule.

B. Ordering and Referring Covered Items and Services for Medicare Beneficiaries

1. Background

Section 1833(q) of the Act requires that claims for items or services for which payment may be made under Part B and for which there was a referral by a referring physician shall include the name and the unique identification number of the referring physician. Physicians are doctors of medicine and osteopathy, optometry, podiatry, dental medicine, dental surgery, and chiropractic.

In the past, prior to the Medicare implementation of the NPI on May 23, 2008, physicians and eligible professionals were identified in claims as ordering or referring suppliers by their Unique Physician Identification Numbers (UPINs). Further discussion on Medicare's use of UPINs can be found in the IFC (75 FR 24441 and 24442). Physicians and eligible professionals applied for and were assigned UPINs as part of the process of enrolling in the Medicare program; therefore, physicians and eligible professionals were expected to be identified in claims as ordering or referring suppliers by their UPINs.

Analysis of Medicare claims data prior to 2008 (UPINs were not permitted to be used in Medicare claims after May 23, 2008) revealed that unauthorized and incorrect use of UPINs was widespread and, as a result, we had reason to believe that many physicians and eligible professionals were unaware of the requirement that their assigned UPINs were intended to uniquely identify them as ordering or referring suppliers and, more importantly, that they needed to apply for UPINs. As a result, Medicare may have paid claims for covered ordered and referred items and services that may have been ordered or referred by professionals who were not of a profession eligible to order and refer; by physicians or eligible professionals who were not enrolled in the Medicare program; or by physicians or eligible professionals who were not in an approved Medicare enrollment status (for example, they were sanctioned, their licenses were suspended or revoked, their billing privileges were terminated, or they were deceased).

With the Medicare implementation of the NPI in May 2008, Medicare discontinued the assignment of UPINs and no longer allowed UPINs to be used in Medicare claims. Because physicians

and non physician practitioners are eligible for NPIs, only the NPI may be used in Medicare claims to identify ordering and referring suppliers. To ensure the unique identification of ordering and referring suppliers and that they were qualified to order and refer, Medicare implemented claims edits in 2009 that require the ordering and referring suppliers identified in Part B claims for items of DMEPOS and services of laboratories, imaging suppliers, and specialists be identified by their legal names and their NPIs and that they have enrollment records in PECOS. The claims edits implemented in 2009 do not result in nonpayment. However, claims edits are under development to ensure that claims for Part B covered items and services (specifically DMEPOS, imaging and clinical laboratory services) and Part A and Part B home health services covered under this final rule identify the physicians and eligible professionals who ordered the item or services by their legal names and their NPIs and that those physicians and eligible professionals have enrollment records in Medicare.

2. Provisions of the Affordable Care Act

Section 6405(a) of the Affordable Care Act amended section 1834(a)(11)(B) of the Act to specify, with respect to suppliers of durable medical equipment, that payment may be made under that subsection only if the written order for the item has been communicated to the DMEPOS supplier by a physician who is enrolled under section 1866(j) of the Act or an eligible professional under section 1848(k)(3)(B) who is enrolled under section 1866(j) before delivery of the item. Section 1128J(e) of the Act requires that he or she be identified by his or her NPI in claims for those services. Medicare requires the ordering supplier (the physician or the eligible professional) to be identified by legal name and NPI in the claim submitted by the supplier of DMEPOS.

Section 6405(b) of the Affordable Care Act, as amended by section 10604 of the Affordable Care Act, amended the Act, and establishes new requirements for home health services. These provisions amended: (1) Section 1814(a)(2) of the Act and specifies, with respect to home health services under Part A, that payment may be made to providers of services if they are eligible and only if a physician enrolled under section 1866(j) of the Act certifies (and recertifies, as required) that the services are or were required in accordance with section 1814(a)(1)(C) of the Act; and (2) section 1835(a)(2) of the Act specifies, with respect to home health services

under Part B, that payments may be made to providers of services if they are eligible and only if a physician enrolled under section 1866(j) of the Act certifies (and recertifies, as required) that the services are or were medically required in accordance with section 1835(a)(1)(B) of the Act. Section 1128J(e) of the Act requires that the physician be identified by his or her NPI in claims for those services. Medicare requires the ordering supplier (the physician) to be identified by legal name and NPI in the claim submitted by the provider of home health services.

In addition, section 6405(c) of the Affordable Care Act gives the Secretary the authority to extend the requirements made by subsections (a) and (b) to all other categories of items or services under title XVIII of the Social Security Act, including covered Part D drugs as defined in section 1860D–2(e) of the Act, that are ordered, prescribed, or referred by a physician enrolled under section 1866(j) of the Act or an eligible professional under section 1848(k)(3)(B) of the Act. Section 1128J(e) of the Act requires that he or she be identified by his or her NPI in claims for those services. Medicare requires the ordering or referring supplier (the physician or the eligible professional) to be identified by legal name and NPI in the claims submitted by the suppliers of laboratory, imaging, and specialist services. These amendments are effective on or after July 1, 2010.

3. IFC Requirements Regarding Ordering and Referring of Covered Items and Services for Medicare Beneficiaries

a. Claims From Providers and Suppliers for Ordered/Referred Part B DMEPOS, Imaging, Laboratory, Specialist Items/Services (§ 424.507(a)(1))

The IFC required that claims from Part B providers and suppliers for covered ordered or referred items or services (excluding home health services and Part B drugs) meet the following requirements:

- The Part B items and services must have been ordered or referred by a physician or, when permitted by regulation or law, by an eligible professional.
- The claim from the Part B provider or supplier must contain the legal name and the NPI of the physician or the eligible professional who ordered or referred the item or service.
- The physician or the eligible professional who ordered the Part B item or service must have an approved enrollment record or a valid opt-out record in PECOS.

The IFC also required that if the Part B items or services were ordered or

referred by a resident or an intern, the claim must identify the teaching physician as the ordering or referring supplier, and the teaching physician must be identified in the claim by his or her legal name and NPI, and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

b. Claims From Medicare Beneficiaries for Ordered/Referred Part B DMEPOS, Imaging, Laboratory, Specialist Items/Services (§ 424.507(a)(2))

The IFC stated that claims from Medicare beneficiaries for ordered or referred covered Part B items and services (excluding home health services and Part B drugs) must meet the following requirements:

- The Part B items and services must have been ordered or referred by a physician or, when permitted by regulation or law, an eligible professional.
- The claim must contain the legal name of the physician or the eligible professional who ordered or referred the item or service.
- The physician or the eligible professional who ordered or referred the item or service must have an approved enrollment record or a valid opt-out record in PECOS.

The IFC stated that if the Part B items or services were ordered or referred by a resident or an intern, the claim must identify the teaching physician as the ordering or referring supplier, and the teaching physician must be identified in the claim by his or her legal name, and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

c. Claims From Providers for Ordered Part A and Part B Home Health Services (§ 424.507(b)(1))

The IFC stated that claims from home health agencies for covered Part A or Part B home health services must meet these requirements:

- The Part A or Part B home health services must have been ordered by a physician.
- The claim must contain the legal name and the NPI of the physician who ordered the service.
- The physician who ordered the service must have an approved enrollment record or a valid opt-out record in PECOS.

The IFC stated that if the Part A or Part B home health services are ordered by a resident or an intern, the claim must identify the teaching physician as the ordering or referring supplier. The teaching physician must be identified in the claim by his or her legal name and

NPI, and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

d. Claims From Beneficiaries for Ordered Part A and Part B Home Health Services (§ 424.507(b)(2))

The IFC required that claims from Medicare beneficiaries for ordered covered Part A or Part B home health services must meet the following requirements:

- The Part A or Part B home health services must have been ordered by a physician.
- The claim must contain the legal name of the physician who ordered the services.
- The physician who ordered the services must have an approved enrollment record or a valid opt-out record in PECOS.

The IFC stated that if the Part A or Part B home health services are ordered by a resident or an intern, the claim must identify the teaching physician as the ordering or referring supplier, and the teaching physician must be identified in the claim by his or her legal name, and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

e. Rejecting Claims From a Provider or Supplier That Do Not Meet the Requirements (§ 424.507(a)(1) or § 424.507(b)(1) Through § 424.507(c))

The IFC provided that a Medicare contractor will reject a claim from a provider or a supplier for covered ordered or referred items and services described in § 424.507(a) and (b) if the claim does not meet the requirements of § 424.507(a)(1) (for Part B items and services except Part B home health services and Part B drugs) and § 424.507(b)(1) (for Part A and Part B home health services).

f. Denying Claims From Medicare Beneficiaries That Do Not Meet the Ordering/Referring Supplier Requirements (§ 424.507(d))

The IFC stated that a Medicare contractor may deny a claim from a Medicare beneficiary for covered ordered or referred items and services described in § 424.507(a) and (b) if the claim does not meet the requirements of § 424.507(a)(2) (for Part B items and services except Part B home health services and Part B drugs) and § 424.507(b)(2) (for Part A and Part B home health services).

4. Summary of and Responses to Public Comments Regarding Ordering and Referring of Covered Items and Services for Medicare Beneficiaries

As a point of clarification, we use the term “ordering/referring provider” in this preamble because that is the terminology used in the implementation specifications for the standard Part B claim format and in the Part B paper claim to denote the individual (the person) who ordered, referred, or certified an item or service reported in that claim. The term “ordering/referring provider” is used in several contexts in this final rule. The term “order” for instance, refers to a provider who orders non physician items or services for the beneficiary, such as DMEPOS, clinical laboratory services, or imaging services. A “certifying” provider generally means a person who orders/certifies home health services for a beneficiary.

The terms “ordered,” “referred,” “certified,” and “ordering or referring” and “ordered or referred” are often used interchangeably within the health care industry and were used interchangeably by parties that commented on the IFC. Generally, we have used the terms applicable to this final rule, which are “ordered” when referring to items of DMEPOS, imaging and clinical laboratory services, and “certified” when referring to home health services. However, to be technically correct in every instance of the use of these terms in this preamble would require that we qualify every use in each instance. We believe that would be cumbersome and unnecessary and, therefore, did not do so. However, the regulatory text uses the technically correct terms.

a. Technical, Administrative, and Procedural Modifications and Corrections

Comment: Several commenters suggested that the agency did not provide a valid rationale for avoiding the procedural safeguards specified in sections 1871(a)(2) and (b)(1) of the Act, which address rulemaking. Moreover, they stated that the statute (at section 6405(a) of the Affordable Care Act) merely authorized the Secretary to require a PECOS enrollment date of July 1, 2010 but did not require it.

Response: Section 6405 of the Affordable Care Act requires physicians or eligible professionals who order or refer DMEPOS or home health services be enrolled in Medicare under section 1866(j) of the Act, and authorizes the Secretary to extend those requirements to other Medicare services. Section 6405(d) of the Affordable Care Act states that the amendments made by section

6405 of the Affordable Care Act “shall apply to written orders and certifications made on or after July 1, 2010.” We find section 6405(d) of the Affordable Care Act to be a clear statutory imperative.

Section 6406 of the Affordable Care Act requires physicians to retain necessary documentation and provide access to records for orders, referrals, and certifications for home health services, DMEPOS, and other items and services as designated by the Secretary, upon request. Section 6406(d) of the Affordable Care Act states “the amendments made by this section shall apply to orders, certifications, and referrals made on or after January 1, 2010.”

These two provisions fall within the exception to section 1871 of the Act that generally requires us to issue a notice of proposed rulemaking prior to issuing a final rule under the Medicare program.

Section 1871(b)(1)(b) of the Act provides that the Secretary is not required to issue a notice of proposed rulemaking before issuing a final rule if “a statute establishes a specific deadline and the deadline is less than 150 days after the date of enactment of the statute in which the deadline is contained.” Section 6405 of the Affordable Care Act establishes an effective date of July 1, 2010, 100 days after March 23, 2010, and section 6406 of the Affordable Care Act established an effective date of January 1, 2010 that passed before the Affordable Care Act was enacted. Additionally, implementing section 6402(a) of the Affordable Care Act, which adds section 1128J(e) to the Act and requires the use of the NPI on all enrollment applications and claims, does not add significant new burdens because the Medicare and Medicaid programs had already required the NPI on claims, applications, and agreements. The Affordable Care Act instructed the Secretary to promulgate a rule that adds this requirement no later than January 1, 2011, and the IFC executed that authority. Finally, a delay in implementing these provisions would be contrary to the public interest and to our efforts to reduce and eliminate fraud and abuse in the Medicare and Medicaid programs. For these reasons, we found good cause to waive the notice of proposed rulemaking and to issue these provisions on an interim final basis.

Additionally, the IFC carried a 60-day public comment period, to be followed by the publication of a final rule, as would a proposed rule. As a result, the public was afforded an opportunity to comment.

Comment: A commenter stated that the Affordable Care Act names DMEPOS and home health services as the only ordered or referred items or services to which the statutory requirements apply. While the law allows CMS to expand the scope, which CMS did by including laboratory services, there is no compelling reason for CMS to have done so.

Response: As stated by the commenter, section 6405(c) of the Affordable Care Act permits the Secretary to extend the requirement to all other categories of items or services under title XVIII of the Act, including covered Part D drugs as defined in section 1866(j) of Act. As noted in the regulation text at § 424.507(a), this regulation has extended the requirements to both laboratories and imaging services. We believe that in the past, some laboratories have abused the reporting of the ordering or referring provider by reporting surrogate UPINs for the ordering or referring providers in all of their claims, when UPINs were permitted to be used in Medicare claims, instead of reporting UPINs that had been assigned to specific physicians or other eligible professionals. These laboratories have also used a single (the same) NPI to identify the ordering or referring providers in all of their claims, having had earlier claims paid when using that NPI. Later, many laboratories used their own NPIs as the NPI of the ordering or referring providers even though the NPI Registry and the NPPES downloadable file were readily available for determining the NPI of the ordering or referring provider. We believe that these are compelling reasons to impose ordering or referring provider edits on clinical laboratory service claims.

Additional efforts to ensure accuracy of claims has also led us to impose NPI requirements on Part D sponsors through the final rule with comment period titled, “Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2013” published in the April 12, 2012 **Federal Register**. This rule requires Part D plan sponsors to submit an active and valid individual prescriber NPI on all prescription drug event (PDE) records submitted to CMS. This rule does not require all physician prescribers to enroll in Medicare. Rather, it mandates that PDE records include active and valid individual prescriber identifiers effective for January 1, 2013 dates of service and later.

Comment: A commenter noted that laboratory services were not subject to the provisions of the Affordable Care Act; therefore, if CMS exercises its

statutorily-given discretion and determines that they must meet the requirements of the IFC, CMS should give laboratories until January 3, 2011 to be in compliance and must allow laboratories to continue to use their own NPI as the ordering or referring provider's NPI until that date.

Response: As stated previously, section 6405(c) of the Affordable Care Act permits the Secretary to extend the requirement to all other categories of items or services, including laboratories. The NPI is the primary metric for us to verify Medicare enrollment and for that reason the two requirements are being implemented simultaneously, as described in the preamble of this final rule. We have been validating the ordering or referring providers reported in clinical laboratory claims since October 2009 to ensure they are properly identified in the claims and have enrollment records in PECOS or in a Medicare legacy system as of the claim receipt date. Such claims have not been denied or rejected due to the lack of the ordering or referring provider's enrollment record. However, our revalidation of the enrollment records in PECOS or a Medicare legacy system has allowed us to alert these providers that they do not have an enrollment record. Clinical laboratories have information available to them that will indicate the NPI of the physicians and other eligible professionals who order services from them. Therefore, we will not permit clinical laboratories to report their own NPIs as the NPIs of the ordering or referring providers. We have not modified the compliance date.

Comment: A commenter stated that the Affordable Care Act does not give the Secretary the authority to determine who may order or refer items or services that are not covered and for which payment will not be made under a Federal insurance plan. The commenter stated that State medical practice acts determine the scope of practice of professionals, and that this regulation is creating a Federalism issue.

Response: We agree with the commenter in so far as this rule does not establish who may order or refer items or services that are not covered and for which payment will not be made under a Federal insurance plan. Although this rule finalizes conditions of payment for ordered items and services, it does not address broader payment policy questions. Rather, this rule implements the statutory requirement that individuals who order and certify particular Medicare-covered services be enrolled in the Medicare program. The Medicaid provisions relating to ordering

and referring were finalized in a February 2, 2011 final rule (76 FR 5862).

Comment: Several commenters noted that the word “must” was omitted from the regulatory text at § 424.506(c), there was a typographical error in another word in § 424.506(c), and noted the omission of the word “claim” in the regulatory text at § 424.507(a)(1).

Response: We have corrected these errors.

Comment: Several commenters indicated that the preamble discussed requirements for those who order DMEPOS, laboratory, imaging, and specialist services, whereas the text at § 424.507 indicates that the requirements apply to “Part B items and services (excluding home health services and Part B drugs),” which is broader in scope than what was discussed in the preamble.

Response: We have revised the regulatory text in this final rule at § 424.507 to be consistent with the language in the preamble with respect to clinical laboratory and imaging services. Further, specialist services are discussed in greater detail later in this final rule.

b. Terminology

Comment: A commenter stated that under Federal law, claims for which payment may be made under Part B and for which there was a referral by a physician must include the name and the UPIN of the referring physician. The commenter stated that this provision incorporates the Stark law definition of “referral,” and the preamble suggests the term “referral” should be interpreted in that manner.

Response: Based upon review of the public comments received, we have decided to remove specialist services from the requirements of this rule. The covered items and services for this final rule include imaging and clinical laboratory services, DMEPOS, and home health. The terms “ordered” and “certified” more accurately reflect these covered items and services. Therefore, we have removed reference to “referrals” in our regulatory text, due to the exclusion of specialist services from this final rule.

Comment: Several commenters requested that CMS define “specialist services,” as there is no requirement that a Medicare beneficiary obtain a referral from a physician to receive services from another physician, particularly since Medicare no longer pays for consultations. Another commenter stated that, because patients can determine for themselves the need to see a specialist, it will be difficult for Medicare claims contractors to

determine that a referring physician should have been reported on a claim. Also, the commenters questioned how a contractor would know that the visit to the specialist was not based on the patient's own decision and not that of another physician.

Response: We agree with the commenters that there are a number of operational issues associated with a requirement that services of a specialist be ordered or referred. We have removed such requirements from this rule.

Comment: Several commenters questioned what is meant by "imaging services" and "imaging suppliers." Commenters questioned if the term applies only to the technical component of imaging services (or global services) or if it also applies to the professional component. They also requested clarification on whether claims for imaging services provided in the hospital outpatient setting would be affected, if independent diagnostic testing facilities (IDTFs) and portable x-ray suppliers are considered "imaging suppliers", and if "services" apply to claims for routine x-rays performed in a physician's own office.

Response: The IFC and this final rule specifically refer to the technical components of imaging services that are: (1) Ordered by physicians and, where permitted, other eligible professionals; (2) furnished by IDTFs, mammography centers, portable X-ray facilities, and radiation therapy centers that are enrolled in Medicare via the CMS-855B; and (3) billed by these Part B suppliers to the Part B claims system (MCS) on an X12N 837P or a paper form CMS-1500.

Comment: A commenter stated that dentists order few clinical laboratory tests but frequently submit orders to dental laboratories, and the items and services provided by dental laboratories are unlikely to be covered by Medicare; thus, such orders and services would pose little risk of waste and abuse of Medicare funds. The commenter urged CMS to define "laboratory" as to exclude dental laboratories in order to clarify dentists' compliance requirements and to relieve dentists of an unnecessary compliance burden.

Response: We do not believe that dental laboratories should be excluded from the requirements of this final rule. We decline to define laboratories in this final rule; however, dental laboratories are, in fact, laboratories. These laboratories, from time to time, provide covered services under the limited circumstances in which dental services are covered by Medicare.

c. Beneficiary Submissions

Comment: Several commenters noted that the IFC contains requirements for beneficiary-submitted claims for home health services. These commenters stated that Medicare home health payments may only be made to Medicare certified home health agencies under assignment, not to beneficiaries.

Response: The commenter is correct in that beneficiaries do not submit claims to Medicare for home health services. This is because home health agencies are obligated by their institutional provider agreement to do all of the billing for services that may potentially be covered by Medicare. Therefore, we are removing the requirement that was added at § 424.507(b)(2) of the IFC and have revised the language in other sections of this rule in accordance with this change.

Comment: A commenter stated that there is no mechanism for ordered or referred items and services to be billed to a beneficiary when the beneficiary requests that the provider or supplier submit a claim to Medicare (which providers and suppliers are required to do under Medicare rules) in situations where the provider or supplier is aware that the ordering or referring provider does not have an approved enrollment record or a valid opt-out record in PECOS.

Response: We adhere to a longstanding position that if a beneficiary receives services that are certified by a physician who is not enrolled in Medicare and if that certifying physician refuses to enroll so that a proper claim can be submitted on the beneficiary's behalf, then the beneficiary cannot be charged for those services. A provider or supplier may be able to avoid the circumstances described in the comment if they ask the ordering or certifying provider if they are enrolled in Medicare before the ordered or certified services have been provided.

d. Effective/Implementation Dates

Comment: A commenter pointed out that the preamble stated that CMS expects that most, if not all, enrolled physicians and other eligible professionals who do not have enrollment records in PECOS, would have submitted enrollment applications by the end of 2010. Therefore, having an effective date of July 6, 2010 for claims to be rejected if they do not have records in PECOS is very confusing.

Response: The statement in the preamble was meant to convey the historical transition and progression of program enrollment requirements that

occurred prior to the passage of the Affordable Care Act, and that physicians and eligible professionals had been complying with the previously stated deadline of January 3, 2011. However, it does not preempt the effective date stated in the IFC. The effective date for the provisions contained in sections 6405 and 6406 of the Affordable Care Act, remains July 6, 2010. Because this rule was issued as an interim final rule with comment period, the provisions that implemented the statutory provisions became effective 2 months after the publication in the **Federal Register**. That interim final rule remains in effect until modified and finalized by this final rule.

Comment: A commenter stated that the Affordable Care Act gives CMS the authority and discretion to maintain the original published deadline of January 3, 2011 and urged CMS to adhere to that previously announced deadline.

Response: As stated in an earlier response, section 6405(d) of the Affordable Care Act states that the amendments made by section 6405 "shall apply to written orders and certifications made on or after July 1, 2010." We find section 6405(d) of the Affordable Care Act to be a clear statutory imperative.

Comment: Multiple commenters expressed concern that the July 1, 2010 date provided 6 months less time to implement these requirements than previously stated by CMS. Commenters believed that the date leaves inadequate time for CMS to notify the affected physicians (especially those who order home health services) and eligible professionals of the requirement to establish an enrollment record in PECOS if one does not already exist. These commenters believed the July 6, 2010 date created an undue burden on many providers, especially large medical groups, because many of their physicians and other professionals are affected by this requirement, creating an enormous workload on them, as well as the CMS contractors. Other commenters believe that the Medicare enrollment application for physicians is lengthy and complex and takes a great deal of time to complete, and requires details and supporting documents that only the physician would be able to provide. The commenters also stated that there are postal delays when mailing applications, and that physicians and their staff schedule vacations around that time of year.

Response: The commenters have referenced an announcement during an open door forum in February of 2010 wherein we noted a delay of in the enforcement of the requirement to enroll

in PECOS to January 2011. However, this delay was preempted by the new statutory effective date in the Affordable Care Act, passed on March 23, 2010. The Affordable Care Act includes amendments to the Act that apply to written orders and certifications made on or after July 1, 2010. Because we must follow the statutory effective date, we have instituted these regulations accordingly.

To provide the physician and eligible professional communities with the opportunity to comply with this regulation, we have made some modifications to the final rule which we believe will assist in that effort. The Affordable Care Act mandated that physicians and eligible professionals who order and refer must be enrolled in Medicare, the program. This final rule mandates the same, mirroring the statutory language. The IFC required an enrollment in PECOS, our data repository system for storing enrollment records. The Medicare legacy systems predate the PECOS system. However, those systems are being phased out and in the near future will no longer be used. At this time, the only way to enroll in Medicare is to establish an enrollment record in PECOS. We have been working towards fully populating PECOS and transferring those providers and suppliers in the legacy systems over to PECOS. This is being done by requiring that providers and suppliers revalidate their enrollment records, which we have separate and established authority to do. By revalidating, providers and suppliers will then have an enrollment record in PECOS. Those physicians and eligible professionals who only have an enrollment record in a local legacy system have been asked to revalidate first, so that they may be included on the Ordering Referring Report (explained in subsequent responses). We have made it clear to the physician and eligible professional communities that we would not turn on the automated edits that would cause a claim not to be paid until all physicians and eligible professionals have been asked to revalidate and have been given the opportunity to complete that process through their respective Medicare Administrative Contractors (MACs). In this final rule, although we have expanded our requirement from requiring enrollment in PECOS to one requiring enrollment in Medicare, which includes enrollment in PECOS or the local legacy systems, our requirements have not practically changed.

We believe that the aforementioned modification of the IFC will not create an additional burden because

information will be gathered through the normal revalidation process. To address the commenters' concerns regarding the lengthy enrollment forms, we have modified the enrollment process for those enrolling only to order and certify. The CMS-855O form is available now for use and is significantly shorter than the original enrollment forms. Additionally, although those physicians and eligible professionals who wish to enroll in Medicare to order and certify, but do not wish to bill the Medicare program, will need to provide information to us via the CMS-855O form, they will not be required to submit financial information, including filling out a CMS-588 Electronic Funds Transfer (EFT) form. We believe that these modifications have addressed the concerns raised by these commenters.

Comment: A commenter suggested that CMS should delay implementation of these requirements until 5 percent or fewer physicians and other eligible professionals lack approved enrollment records or valid opt-out records in PECOS.

Response: The Affordable Care Act requires that physicians who order certain items or services must be enrolled in Medicare. As previously stated, we have changed the enrollment requirement from one mandating enrollment in PECOS to one requiring enrollment in Medicare—including PECOS or other legacy Medicare enrollment systems. In addition, as we have indicated in this final rule and in open door forums, we have not yet activated the automated edits that would cause claims for services or supplies not to be paid for lack of an approved enrollment record in Medicare. We will provide advance notice of activation of the automated edits. We believe these changes alleviate the concerns of the commenter.

Comment: A commenter suggested that if the July 6, 2010 date remains in effect, consideration should be given to processing and paying claims if the ordering or referring provider has an enrollment application in process at a CMS contractor.

Response: We have changed the enrollment requirement from one requiring enrollment in PECOS to one requiring enrollment in Medicare—including PECOS or other legacy Medicare enrollment systems. However, physicians and eligible professionals must have an approved enrollment record in Medicare, not a pending record in Medicare to order and certify services for Medicare beneficiaries.

Comment: Several commenters questioned whether the practice of

providers billing for services after July 6, 2010 and the ordering or referring provider's failure to have a record in PECOS at that time, could trigger liability under the False Claim Act.

Response: The False Claims Act (FCA), 31 U.S.C. 3729 through 3733, imposes civil liability for the knowing submission of a false or fraudulent claim for payment and the Department of Justice investigates and litigates alleged FCA violations. Therefore, any question related to FCA liability is beyond the scope of this rule.

Comment: Another commenter asked if providers that submitted claims between July 2010 and December 2010 that fail the edits because the ordering or referring provider or eligible professional did not have an enrollment record in PECOS may eventually be held liable for non-compliance and could face rejected claims and recoupment by Zone Program Integrity Contractors (ZPICs), Contractor Error Rate Testing (CERT), Durable Medical Equipment Medicare Administrative Contractors (DME MACs), and Recovery Audit Contractors (RACs), and other contractors at any point after July 1, 2010, noting that a tremendous number of claims would have failed those edits during that timeframe.

Response: We have delayed the implementation of automated edits that would cause a claim not to be paid due to the lack of an approved enrollment record in Medicare for the ordering or certifying physician or eligible professional. This final rule does not in any way provide relief to providers whose claims would be subject to recoupment by any CMS contractor, including ZPICs, RACs, and MACs, as well as any law enforcement partner, due to improper payments resulting from any other reason unrelated to the ordering or certifying requirements. We always retain the right to pursue fraud and recoup money for claims that did not meet the requirements of the IFC. However, for operational reasons, we do not believe it would be a prudent use of resources to pursue large-scale recoveries against claims with dates of service from July 2010 until such time as we activate prepayment edits that identify claims that do not have proper documentation of enrolled ordering and/or certifying suppliers.

Comment: Commenters stated that claims for home health services are reimbursed on a 60-day episode basis, and claims submitted on or after July 6, 2010 would be for services provided in April, May, and June. The commenters stated that because the IFC was published on May 5, 2010, it may apply to home health services ordered before

May 5, and would not be fair to require retroactive compliance with a new regulation.

Response: We will provide advance notice to providers and suppliers of the date we plan to activate the automated edits that would cause a claim not to be paid for the lack of an enrollment record in Medicare. No part of this final rule will require retroactive compliance for periods of time before July 6, 2010. Further, the edits will apply to only those claims with a date of service on or after the date the edits are activated.

Comment: Commenters argued that the July 6, 2010 date should apply only to orders and referrals for DMEPOS and home health services, as those are the only ordered or referred items or services specifically named in the Affordable Care Act, and that those who order or refer imaging, laboratory and specialist services (which are not named in the law but CMS names in the IFC) should have been given until January 3, 2011 to enroll/re-enroll. Similarly, another commenter stated that laboratory services were not subject to the provisions of the Affordable Care Act; therefore, if CMS exercises its statutorily-given discretion and determines that they must meet the requirements of the IFC, CMS should have given laboratories until January 3, 2011 to be in compliance.

Response: Extending the ordering and referring enrollment requirements to other providers and suppliers is permitted by statutory provisions in 6405(c) of the Affordable Care Act, including laboratory and imaging services. However, as noted in the responses to comments, we have eliminated from the final rule the requirements related to referrals to physician specialists. The statutory effective date is binding for all applicable provisions of this rule, including those specifically mandated in the Affordable Care Act provisions, as well as those added at the discretion of the Secretary. Therefore, we are not able to make the suggested change.

Comment: Several commenters stated that CMS should flag claims with a date of service after July 6, 2010 that have been rejected due to the ordering or referring provider not having an enrollment record in PECOS and that CMS should then communicate this information to the billing provider and CMS should use this information to target outreach to non-PECOS ordering or referring providers. Some commenters stated that physicians do not understand why other providers/suppliers, instead of CMS, are notifying them of the need to have records in PECOS.

Response: As stated previously, Medicare contractors have communicated in writing with enrolled physicians and nonphysician practitioners who do not have enrollment records in PECOS and have urged them to establish those records through revalidation. Suppliers who have submitted claims for items and services ordered and referred by non-enrolled physicians have been receiving informational messages that these claims are not in compliance with the enrollment requirements but are not being denied at this time. We are aware that some suppliers have been communicating with those individuals who ordered and referred items and services about the requirement to enroll in Medicare and we encourage all suppliers to do so. We believe that our outreach documents and messages provided at our provider open door forums are clear, comprehensive, and continue to stress the importance of having an enrollment record in PECOS. We will continue our direct outreach with these communities as we implement this final rule.

Comment: Due to the short timeframe for complying with the new provisions, several commenters questioned that we allow the effective date for ordering home health services by newly enrolling physicians be the date the physician mails the signed CMS-855 Certification Statement to the Medicare contractor.

Response: The statute requires that enrollment must be valid based on the date of the order or referral. As noted in the preamble of this final rule, the final rule requires enrollment based on the date of service, not the mailing date of the CMS-855 Certification Statement. In order for a physician or non physician practitioner to be enrolled in Medicare, the Medicare contractor must process the enrollment application to a final approved status. This process could take approximately 45 days or more, depending upon various factors. To allow physicians and eligible professionals sufficient time to enroll to order and certify, we will provide ample notice of our plans to activate the automated edits that will cause a claim not to be paid due to the lack of an approved enrollment record in Medicare to order and certify.

Comment: A commenter stated that because CMS recently implemented the Outcome and Assessment Information Set (Oasis C) for home health agencies, making the effective date of July 6, 2010 in the IFC would be even more onerous and difficult to implement due to such short notice.

Response: The effective date for the enrollment requirements for physicians

and eligible professionals who order and certify covered items and services was mandated by statute. Consequently, we are not able to change the effective date.

e. Enrollment Records, PECOS, FISS, NPPES, and the Ordering Referring Report

Comment: A few commenters questioned why CMS needs PECOS when there is already an NPI database.

Response: PECOS is a Medicare enrollment repository and the “NPI database” (NPPES) is the repository of information about health care providers who have been assigned NPIs and their assigned NPIs. Any health care provider who has an NPI has a record in NPPES. Not all health care providers in NPPES are in PECOS, because not all health care providers with NPIs are enrolled in the Medicare program. Please see the CMS NPI Web page for more information about NPIs and NPPES www.cms.gov/NationalProviderStand/.

Comment: A commenter did not understand why an ordering physician had to have an enrollment record in PECOS when the physician already has an NPI.

Response: Having an NPI does not mean that a physician is enrolled in the Medicare program or that the physician has an enrollment record in PECOS or in Medicare. The Affordable Care Act requires that physicians who order certain items or services must be enrolled in Medicare. We have changed the enrollment requirement language from one requiring enrollment in PECOS to one requiring enrollment in Medicare—including PECOS or other legacy Medicare enrollment systems. This final rule requires that physicians report an NPI on new enrollment records and on submitted claims for payment. We will use our existing authority to revalidate enrolled providers, which will require the reporting of the NPI on an enrollment application.

Comment: A commenter recommended that CMS consider a bi-directional interface between PECOS and NPPES to permit both systems to contain the information necessary for a provider to verify that the ordering or referring physician is a qualified provider of Medicare services.

Response: While we appreciate the commenter's point of view, NPPES is an entirely separate entity from Medicare and PECOS. NPPES simply assigns NPIs and collects the corresponding information for those numbers. NPPES does not collect Medicare enrollment information. PECOS collects Medicare enrollment information, as do CMS's

legacy systems. Medicare verifies the credentials of its enrolling providers and suppliers as part of the provider and supplier enrollment process that occurs when Medicare contractors process Medicare enrollment applications. This verification does not occur when health care providers apply for and are assigned NPIs by NPPEs.

Comment: A commenter stated that providers and suppliers, including practitioners, may not know whether they have NPIs in their enrollment records in PECOS, or what they need to do in order to comply with the NPI requirement to submit the NPIs to CMS by July 6, 2010.

Response: We have established a number of ways for providers and suppliers to inquire about their status with Medicare.

- Providers and suppliers may start by referring to the NPI Registry online to search for their NPI. Those eligible for an NPI, who are enrolled in Medicare, must establish an NPI and update their enrollment records with Medicare.

- Providers and suppliers may also refer to the Ordering Referring Report to verify their enrollment records. The Ordering Referring Report is a report published by CMS that reflects the approval status of all physician and non physician practitioners who have applied to order and refer. The report will show all practitioners who have an approved record in PECOS to order and refer and practitioners who have an application that has been received and is pending approval. The report is available via the following link: http://www.cms.gov/MedicareProviderSupEnroll/06_MedicareOrderingandReferring.asp#TopOfPage.

- Providers and suppliers may also use Internet-based PECOS to view their enrollment records. This will also enable the user to determine whether their NPI is included in their enrollment record in PECOS.

Comment: Several commenters, noting that not all Medicare providers and suppliers who have enrollment records in PECOS have NPIs in those records, believed that the requirement for such providers and suppliers to submit, by July 6, 2010, enrollment applications that contain the NPI would overwhelm the Medicare contractors, as this would be an additional burden on the contractors that already have backlogs of enrollment applications to process. They recommended that CMS issue guidance to its contractors for establishing a process for those who need to establish enrollment records in PECOS, as well as those who need to add their NPIs to their enrollment records, and to hold such providers and

suppliers harmless for failure to submit the required enrollment applications or add their NPIs to their enrollment records prior to having been notified to do so by their designated Medicare contractors.

Response: The Medicare provider/supplier enrollment Web site assists providers and suppliers in determining whether they have enrollment records in PECOS and also provides information on how to enroll. We will continue to convey these messages, as appropriate, via our provider/supplier open door forums, in CMS provider listserv messages, in Medicare Learning Network products, and in our conversations and discussions with national provider and supplier organizations.

As stated previously, we will provide ample notice of our plans to activate the automated edits that will cause a claim not to be paid due to the lack of an approved enrollment record in Medicare to order and certify. Therefore, there is no reason for us to hold providers harmless for failing to be compliant with this requirement.

Comment: Many commenters stated that physicians' practices do not understand the PECOS system and that CMS help is difficult to obtain. The commenter stated that the help number is only available 4 hours per day and providers cannot get through. Another commenter believed the PECOS process to be quite difficult and time consuming.

Response: We have provided PECOS instructional guides for physicians, nonphysicians and DMEPOS suppliers available at: http://www.cms.gov/MedicareProviderSupEnroll/04_InternetbasedPECOS.asp.

The CMS End User Services (EUS) Help Desk operates under our direction and is equipped to respond to operational systems issues related to Internet-based PECOS that are reported by providers and suppliers. Examples of issues that should be reported to the CMS EUS Help Desk include access problems (for example, user ID and password do not work, forgotten User ID or password, help in setting set up User ID or password), difficulty in understanding how to follow the screens in the application process, error messages, and system performance issues. The telephone number of the CMS EUS Help Desk is 1-866-484-8049 (TTY/TDD 1-866-523-4759); the email address is EUSSupport@cgi.com. The CMS EUS Help Desk days and hours of operation are Monday through Friday, 7 a.m. to 7 p.m. Eastern Time. The CMS EUS Help Desk is unable to answer enrollment policy questions; those

questions must be directed to the Medicare contractors. Medicare provider enrollment contact information for each State can be found in the download section of <http://www.cms.gov/MedicareProviderSupEnroll/>.

We will investigate all reports of slowness or similar systems problems that Internet-based PECOS users may experience and report to the CMS EUS Help Desk.

Providers and suppliers with questions regarding the use of PECOS for the enrollment process should contact their jurisdiction's MAC. Although each MAC's hours of operation may vary, their normal business hours are generally established at 8 hours daily. Each MAC is required to comply with certain training exercises; therefore, there may be times when the hours of operation are shortened to 4 hours. The MACs may also be closed on Federal holidays. We do not believe that these limited interruptions significantly impact the MAC's ability to provide assistance related to PECOS due to these limited periods of interruption.

Comment: A commenter stated that CMS has confused physicians unnecessarily by referring to PECOS interchangeably as both an enrollment repository and as a Web site. They think that when they "sign up" to use the Web site, they have enrolled, only to find out that they still need to submit an application, a much more cumbersome process.

Response: Internet-based PECOS is a secure Web site providers can log into and then submit an application to enroll. In order to use Internet-based PECOS, a provider or supplier must log in by entering his or her User ID and password or register to obtain log in information in the PECOS Identity and Access (I&A) System. Logging on or registering is not enrolling or updating an enrollment record. After access to Internet-based PECOS is granted, the user must complete and then submit the enrollment application electronically; then the user must print the Certification Statement and have it signed and dated by the appropriate individual, gather any required supporting paper documentation, and send this material to the designated Medicare contractor. After the designated contractor receives the signed and dated Certification Statement and any additional paper documentation, it begins to process the enrollment application to an approved (approved or opt-out) or disapproved status. Once the application is approved, the provider or supplier will have an approved enrollment record or

a valid opt-out record in PECOS. We have revised some of the material on the Medicare provider/supplier enrollment Web site in an attempt to clarify requirements and processes to address the concerns expressed by the commenter. PECOS can be accessed here: <https://pecos.cms.hhs.gov/pecos/login.do>.

We offer additional information on internet-based PECOS on our Web site. This information includes several Medicare Learning Network (MLN) articles that provide providers and suppliers with in-depth information to assist them in navigating the enrollment process.

Comment: A commenter stated that the “find a doctor” link on the *Medicare.gov* Web site does not inform beneficiaries of the PECOS requirements or indicate whether the physicians it suggests to patients are PECOS enrolled. Another commenter noted that it will be difficult for Medicare beneficiaries to know if their physician has an enrollment record in PECOS. The commenter also stated that if the physician does not have an approved record in PECOS, and he/she orders or refers, and the provider or supplier refuses to furnish the item or service, the beneficiary will develop further health problems, causing more problems for the beneficiary as well as the taxpayer and the provider. Another commenter stated that beneficiaries should be made aware of the impact of these requirements on their ability to access subsequent care.

Response: We use a number of communication vehicles to communicate with beneficiaries about Medicare including the annual *Medicare and You Handbook* describing the program, which refers to the requirements that physicians and eligible professionals, were applicable, who order and certify Medicare services for beneficiaries must be enrolled in Medicare. The *Medicare.gov* Web site uses PECOS as the source of the information it displays about physicians. We are continually updating the information in PECOS to be sure that it is complete and accurate. The Affordable Care Act requires that physicians who order certain items or services must be enrolled in Medicare. We recognize that this requirement may pose issues for beneficiaries who need care and who are unsure whether their physician is enrolled in Medicare. As mentioned earlier in this preamble, there are a number of ways a beneficiary can determine whether a physician is actually enrolled in Medicare, including to ask the physician whether he or she is enrolled. In addition, for ease of

access, we have created the Ordering Referring Report that provides the public, including beneficiaries, information on who is enrolled in Medicare to order and certify (available at http://www.cms.gov/MedicareProviderSupEnroll/06_MedicareOrderingandReferring.asp). To ensure that Medicare beneficiaries are aware of the need for the providers and suppliers from whom they receive items and services to be enrolled in Medicare (even if only to order and certify, when permitted) or to have validly opted-out of Medicare, we will continue to share information with senior citizens’ organizations and create special messages for Medicare beneficiaries about these issues and processes. We believe all of these changes reduce the risk that beneficiaries will be disadvantaged by implementation of the statutory requirements.

Comment: Many commenters stated that the Affordable Care Act requires physicians who order or refer DMEPOS and home health services to be enrolled in Medicare but does not require them to have enrollment records in PECOS, whereas the IFC requires the latter. The commenters suggested that CMS should focus on ensuring that those who order and refer DMEPOS and home health services and who have never enrolled in Medicare, must enroll in Medicare, and CMS should have let those who are enrolled and not yet in PECOS have until January 2011 to get their enrollment information into PECOS. This could help reduce the strain on the enrollment contractors.

Response: The Affordable Care Act requires that physicians who order certain items or services must be enrolled in Medicare. In response to comments, we have changed the enrollment requirement language from one requiring enrollment in PECOS to one requiring enrollment in Medicare—including PECOS or other legacy Medicare enrollment systems. However, as we explained in this preamble, we will be transitioning all legacy system enrollees to PECOS via our revalidation process and will delay the activation of the automated edits. Once implemented, these edits will cause a claim, for the lack of an approved enrollment record in Medicare for the ordering or certifying physician or other eligible professional, not to be paid. These edits will not be activated until the revalidation process is completed for the relevant supplier groups that order and certify. The Affordable Care Act does not authorize the Secretary to arbitrarily implement this rule for certain providers and suppliers who

enroll to order and certify. We believe that the delay of the automated edits alleviates the commenters’ concerns. We require that providers and suppliers be enrolled in the Medicare program or that they have validly opted out of the Medicare program as of the date of service, beginning with dates of service of July 6, 2010. However, as already stated, we will provide advance notice of the activation of the automated edits that pertain to these claims.

Comment: A commenter stated that physicians who have attempted to enroll in order to get their enrollment data into PECOS have had their applications returned to them with instructions that there is no need for their applications to be updated at this time.

Response: We understand that there has been some confusion in the past and have instructed our Medicare contractors to process these applications. Our instructions to the enrollment contractors also state specifically that physicians who are currently enrolled in PECOS and have an NPI in their records need not resubmit an application to enroll to meet the statutory requirements addressed in this final rule. Our enrollment contractors receive on-going training to address these types of issues and we do not expect any confusion in the future.

Comment: Several commenters stated that physicians have used Internet-based PECOS to enroll but their names are not in the Ordering Referring Report available on the CMS Web site at www.cms.gov/MedicareProviderSupEnroll.

Response: We are evaluating the reasons why physicians or other eligible professionals do not appear on the Ordering Referring Report. If a physician or other eligible professional believes that he or she has been omitted from this report in error, we encourage them to contact their respective Medicare contractor for assistance.

Comment: A commenter asked CMS to define what is meant by an “approved enrollment record in PECOS.” Further, the commenter thought that Medicare contractors should retroactively approve each enrollment application found in PECOS to the date the application was initially submitted to CMS. The commenter believed this would be consistent with the effective date of enrollment in Medicare for physicians, non physician practitioners, and physician and non physician practitioner organizations, which is defined at § 424.520(d) as the latter of the first date the individual began furnishing services at a new

practice location or the date of filing of the application that is subsequently approved.

Response: For purposes of this final rule, an ordering or certifying provider must be enrolled in Medicare in an approved or a valid opt-out status as of the date of service on the claim. As the commenter stated, under § 424.520(d), the effective date of Medicare billing privileges for physicians and practitioners is the date of filing of a Medicare enrollment application that is subsequently approved or the date an enrolled physician or non physician practitioner first began furnishing services at a new location, whichever is later. The provider may begin ordering or certifying items and services as of the effective date of his/her Medicare billing privileges.

Comment: Some commenters suggested that CMS provide more information about the Medicare legacy claims system and how providers can access it, as the legacy claims system is another way that ordering or referring providers can be in compliance with existing ordering or referring provider requirements.

Response: Providers are not permitted to access the Medicare legacy claims systems and there is no need for them to do so. In earlier responses, we have explained numerous ways for providers to access the records that provide the information sought by the commenters.

Comment: Several commenters noted that the Ordering Referring Report that is available on the CMS provider/supplier enrollment Web page is difficult to use effectively.

Response: We revised this report so that it is more user-friendly. The Ordering Referring Report is now available on the Medicare provider/supplier enrollment Web site in two formats: PDF and CSV. The PDF format enables a person to search for a particular physician or other eligible professional, either by NPI or by name. We believe these changes have alleviated the problems associated with conducting searches and we will continue working to improve the quality of search capabilities.

Comment: Some commenters requested that the report be made available more frequently, such as daily.

Response: The Ordering Referring Report is replaced at a minimum of once per week. We do not believe that more frequent availability (daily, real-time) is necessary or practical. As mentioned in a previous response, a report of physicians and other eligible professionals whose enrollment applications are in process is also available on the same Web site.

Comment: A commenter stated it has no way of knowing when an enrolled physician establishes an enrollment record in PECOS in order to resubmit a claim that had been submitted but had failed the ordering or referring provider edit.

Response: The Ordering Referring Report is updated at a minimum of once per week and is available in two formats, as noted earlier. By comparing information in a provider's or supplier's previously submitted claims to the information in this file, it is possible to determine if the ordering or certifying providers identified in previously submitted claims are enrolled in Medicare in an approved status or have validly opted-out.

Comment: A commenter stated that PECOS must be updated daily or patients will be incorrectly denied services.

Response: PECOS, the national Medicare FFS provider and supplier enrollment system, is updated daily, and an extract of PECOS enrollment data is transmitted electronically each night to the Medicare claims systems.

Comment: A commenter stated that a physician who received an enrollment letter from CMS could not be found on the Ordering Referring Report.

Response: There were some errors in the generation of the Ordering Referring Reports that were produced in the late spring of 2010 that resulted in the omission of some physicians and other eligible professionals from the Ordering Referring Report. We have corrected the errors.

Comment: Several commenters stated that home health agencies should be given the capability to access the Fiscal Intermediary Standard System (FISS) to research the enrollment status of enrolled and opt-out physicians, as FISS is updated daily.

Response: As stated in an earlier response, providers and suppliers may not access the claims systems. Information regarding a provider or supplier's enrollment status is available by checking the files we post on the Medicare provider/supplier enrollment Web site, or by inquiring with the ordering or certifying providers.

f. Enrollment Applications and Processing

Comment: Commenters stated that Medicare enrollment contractors are not processing enrollment applications in a timely manner, are not providing accurate information to inquiring physicians and others, are not responding timely to questions, and that this made it impossible for those physicians and other practitioners to

have enrollment records in PECOS by July 6, 2010. A commenter asserted that it has taken a total of 90 days or more for contractors to process enrollment applications and for CMS to include the physician in the Ordering Referring Report, making the July 6, 2010 date unacceptable. The commenter also suggested that the new future deadline will put even more of a strain on the Medicare enrollment contractors, who are already behind in processing enrollment applications.

Response: Additional resources have been allocated to Medicare contractors to enable the processing of increased numbers of enrollment applications. Furthermore, we have undertaken many activities to streamline the process and assist the provider and supplier communities in complying with this rule. These include: (1) Modifying the enrollment requirement language from one requiring enrollment in PECOS to one requiring enrollment in Medicare—including PECOS or other Medicare enrollment systems; (2) not immediately activating the automated edits that would cause claims for items or services not to be paid for lack of an approved enrollment record in Medicare; and (3) providing a streamlined application for those providers and suppliers who wish to enroll to order and certify (CMS-855O). We have worked with the provider and supplier community to be responsive to application processing concerns and are continuously working to make the enrollment process faster and easier for the provider and supplier communities.

Comment: Many commenters suggested that CMS increase resources to contractors to ensure that customer service lines are answered promptly including the Internet-based PECOS call center and the NPI Enumerator call center. The commenter also noted that customer service training should be improved, and that information submitted by physicians should not be lost.

Response: We agree with the commenter. We have taken a number of steps to address the commenter's first concern. The CMS EUS Help Desk (the Internet-based PECOS call center) is hiring more staff and is more thoroughly educating its employees on how to properly handle issues and problems related to Internet-based PECOS. We have made improvements in the language used on the screens in Internet-based PECOS to help eliminate confusion. We have also taken steps to ensure the system operates more smoothly and consistently. The NPI Enumerator call center remains fully staffed and funded to assist those

physicians and other eligible professionals who need to obtain or establish NPIs, as well as those who have lost or forgotten their NPPES User IDs and passwords to enable them to use Internet-based PECOS. In addition, we are continuing to make major revisions to the enrollment process that will significantly reduce delays and other problems associated with PECOS enrollment.

Comment: A commenter stated that a Medicare contractor requires physicians to submit multiple CMS-855I and 855R forms, one for each Medicare-assigned Provider Transaction Access Number (PTAN). The commenter was concerned that this is resource-intensive on the physician and the contractor.

Response: We do not require physicians or other eligible professionals to submit multiple enrollment applications (CMS-855I forms) in situations where they have more than one PTAN unless the PTANs represent practice locations that exist in more than one Medicare contractor jurisdiction. In that situation, a physician or other eligible professional would need to submit an enrollment application to each Medicare contractor; a Medicare contractor has access only to the PECOS enrollment records with practice locations within that contractor's jurisdiction. The 855R form is not an enrollment application, as such. This form is used to reassign benefits to another provider or supplier, such as a physician group practice. This has a very different function than the standard enrollment forms. Additionally, in an effort to streamline our enrollment for this final rule, we have developed the new CMS-855O form. This form will be available to those physician and nonphysician practitioners who wish to submit an enrollment application just for the purposes of ordering and certifying.

Comment: A commenter stated that the enrollment processing time should be more reasonable, such as 7 to 14 days.

Response: Many of the applications submitted to the Medicare contractors are processed in as little as 14 days. However, Medicare contractors must verify information reported in the Web-based and paper enrollment applications, and sometimes need to obtain additional information or clarification from enrolling providers and suppliers. Providers and suppliers are not always timely in furnishing the requested clarifications or additional information, which may add substantially to the processing time and, if the requested information is not furnished within the timeframe required

by the Medicare contractor, it may cause an enrollment application to be rejected. Paper enrollment applications take longer to arrive at the Medicare contractors and take longer to process than those submitted via Internet-based PECOS for several possible reasons related to paper applications that may be missing required data; may contain illogical dates or incorrect, incomplete, missing addresses or telephone numbers; or may be missing required supporting documentation. The increased volume of enrollment applications has resulted in slightly longer processing times. However, since we changed the enrollment requirement from one requiring enrollment in PECOS to one requiring enrollment in Medicare—including PECOS or other Medicare enrollment systems, we believe we have eliminated some of those possible problems and delays in processing during the revalidation process. This change has ensured that claims of existing approved Medicare providers have not been disrupted.

Comment: A commenter stated that CMS should make available data regarding enrollment applications submitted due to these new requirements and detail the success of the Medicare contractors in processing the applications within the required timeframes.

Response: We make available on the Medicare provider/supplier enrollment Web site a report showing the legal names and NPIs of physicians and other eligible professionals who have enrollment applications being processed by the Medicare contractors. For purposes of this final rule, we do not believe it appropriate to include the enrollment application processing times of the Medicare contractors. Many factors influence the time it takes to process an enrollment application, including the method (Web or paper) by which the enrollment application was submitted and the completeness of the application. Medicare contractors have several methods available to them for managing their workloads successfully. However, we do monitor application processing activities for timeliness and other performance variables.

Comment: A commenter stated that the IFC expanded the scope of the statute by including radiology and pathology services as ordered or referred items and services. The commenter asserted that many more physicians order these services than order DMEPOS, and that CMS has not permitted adequate time for physicians to become aware of this expansion and, if necessary, establish enrollment records in PECOS. The commenter

asked that CMS determine the number of physicians who must establish enrollment records in PECOS and then establish manageable timeframes for processing the revalidations. The commenter suggested that CMS also consider having the Medicare contractors create special processing units to process only voluntary revalidation applications.

Response: Section 6405(c) of the Affordable Care Act permits the Secretary to extend the requirement to all other categories of items or services, including imaging services and clinical laboratory services. We have a general sense of the pool of affected physicians and other eligible professionals who must establish enrollment records in Medicare and have established manageable timeframes for processing the revalidations. Additionally, we have engaged in outreach efforts with the impacted medical communities. As a result, those who order imaging services and clinical laboratory services should be fully aware that they need to be enrolled in Medicare or have validly opted-out of Medicare to continue to order those services. We do not believe there is a need to provide additional time for those who order imaging services and clinical laboratory services to enroll in Medicare.

By "voluntary revalidation applications," we believe the commenter is referring to enrollment applications submitted by enrolled physicians and other eligible professionals absent the receipt of a revalidation letter from a Medicare contractor. Revalidation requests are generated by Medicare contractors, and providers and suppliers are given a specific period of time in which to submit their enrollment applications. Medicare contractors give priority to processing all initial enrollment applications and to those who are enrolling just to order and certify. We do not accept voluntary revalidation applications and we do not intend to in the future.

g. CMS Outreach Activities and Education

Comment: Commenters stated that home health agencies, who learned of these requirements when reading the IFC, need time to educate physician and hospital communities on the dual issues of the physician status in PECOS and potential adverse impact on access to post-acute care services for their patients. A commenter requested that if the July 6, 2010 date for the ordering or referring supplier requirement for physicians is not moved to January 3, 2011, CMS should—(1) Fund

enrollment contractors for physician outreach and enrollment application processing; (2) direct contractors to set up dedicated lines to expedite inquiries and resolve problems related to enrollment and PECOS; and (3) send out messages through electronic means, set up open door meetings, and utilize other DHHS communications tools to ensure physicians are aware of the accelerated deadline and have the ability to meet it.

Response: We agree that provider communication and information is central to the success of the requirements mandated by this final rule. We have implemented a communications plan for the requirements. Furthermore, the delay in the activation of the automated edits and the changes made in this final rule will assist the provider and supplier communities in complying with this rule. We will continue to convey these messages via open door forums, Medicare Learning Network articles, and other venues.

Comment: Many commenters stated that CMS should develop an aggressive outreach enrollment campaign for physicians, as they may be unaware of the need to establish enrollment records in PECOS if they are enrolled and do not have records in PECOS, and they may be unaware of the requirement to report their NPI on a Medicare enrollment application if they were enrolled and later obtained their NPI and have not yet reported it to Medicare on a Medicare enrollment application.

Response: As previously stated, we have changed the enrollment requirements on mandating enrollment in PECOS to one requiring enrollment in Medicare—including PECOS or other legacy Medicare enrollment systems. We have pursued an aggressive outreach initiative to educate the provider and supplier communities on the ordering and referring requirements even before the IFC was published on May 5, 2010. Upon publication of this final rule, we plan to disseminate guidance on specific provisions of the final rule by producing a Medicare Learning Network product, placing additional or revised information on the Medicare provider/supplier enrollment Web site, making announcements at CMS provider/supplier open door forums, and releasing messages via CMS provider/supplier listservs and to national senior citizens' organizations.

Comment: A commenter stated that CMS should engage in special outreach efforts to hospital clinics that may not understand that the physician, as well as the clinic, must have an enrollment record in PECOS.

Response: Enrollment has been a longstanding requirement. However, we will be sure to address this in an upcoming update of the applicable informational documents that are available on the Medicare provider/supplier enrollment Web site and we will also continue our outreach efforts to educate the provider and supplier communities.

Comment: A commenter suggested that CMS prepare a model letter and make it available to the supplier community so that the suppliers can forward the letter to those who order items and services who do not have approved enrollment records or valid opt-out records in PECOS.

Response: We have and will continue to reach out to the provider and supplier community by providing educational material using a number of different media. On June 28, 2010, we announced through a Medicare Learning Network article that Medicare contractors would be mailing letters to physicians and non-physician practitioners who are enrolled in Medicare but who do not have enrollment records in PECOS. Our numerous announcements at our provider/supplier open door forums continue to remind physicians and other eligible professionals of our goal of ultimately having all FFS providers and suppliers in PECOS. We believe that these, and other outreach efforts, make it unnecessary to generate a model letter at this time.

Comment: Many commenters suggested that CMS work collaboratively with the medical community to ensure physicians clearly understand their enrollment responsibilities.

Response: We have frequent communications with national medical associations and other groups and organizations. We also deliver provider/supplier enrollment information and messages at the regularly scheduled CMS provider/supplier open door forums. In addition, we have sponsored several open door forums dedicated to Medicare provider/supplier enrollment and will continue to do so as the need arises. We have created, and continue to create, special documents to inform the provider/supplier community of the Medicare enrollment requirements and to assist them in complying with those requirements.

h. Patient Care Implications and Access

Comment: A commenter suggested that the new deadline could potentially cause serious disruption in payments and claim resolution and could adversely affect millions of patients across the United States. Another

commenter stated that CMS is placing an enrollment requirement above the interests of Medicare beneficiaries, and the effective date should remain January 2011.

Response: We have taken action to address the commenter's concern by not activating the automated edits that would cause a claim to not be paid due to the lack of an approved enrollment record in Medicare. In addition, we have made other changes in this final rule to reduce the risk that Medicare beneficiaries will not have access to quality care. Also, our enrollment requirements are an essential program integrity function that permits us to screen providers and suppliers to ensure that beneficiaries are receiving care from licensed, legitimate providers and suppliers. The effective date is mandated by the Affordable Care Act.

i. Impact on Individual Medical Communities

Comment: Commenters suggested that with the July 6, 2010 date, suppliers will be compelled to either furnish the ordered or referred items and services at their own cost or that of the beneficiary or to hold their claims until the ordering or referring supplier has an approved enrollment record or valid opt-out record in PECOS. Both scenarios are unfair to suppliers and beneficiaries because neither have control over physician enrollments in PECOS.

Response: In response to public comment, we changed the enrollment requirement language from one requiring enrollment in PECOS to one requiring enrollment in Medicare, including PECOS or other legacy Medicare enrollment systems, so that those suppliers enrolled in a legacy system can continue to order and certify during the revalidation process. This will alleviate much of the commenters' concern. In addition, we will provide notice well in advance of activation of the automated edits that would cause claims for services or supplies not to be paid for lack of an approved enrollment record in Medicare. At the time we activate the edits, all eligible suppliers will have been given the opportunity to enroll or revalidate enrollment for the purpose of meeting the ordering and certifying requirement. Billing providers and suppliers should continue to assess their business practices of taking orders and certifications from non-Medicare enrolled providers and proceed accordingly. In addition, as stated earlier in this preamble, we have provided alternative approaches for providers and suppliers to verify the enrollment status of individuals who order and certify Medicare services. We

will continue with our extensive outreach efforts so that physicians and eligible professionals have the opportunity to educate themselves on these requirements.

Comment: Several commenters noted that there is no direct incentive to have an enrollment record in PECOS because those who are enrolled, but who do not have records in PECOS, continue to be paid. Some commenters stated that some enrolled physicians told them they will take no action to establish enrollment records in PECOS. Commenters complained that the burden lies on the billing provider or supplier who furnished the ordered or referred items and services to confirm the ordering or referring provider's PECOS status and educate them if they do not have enrollment records in PECOS. Many commenters added that DMEPOS suppliers ultimately have no control over what referring physicians do, yet the DMEPOS suppliers find their livelihoods and businesses, not those of the physicians, to be at risk by this IFC. Another commenter stated that CMS should, in a first phase, only reject the claims from physicians who do not have enrollment records in PECOS and then, once they establish their records in PECOS, in a second phase, reject claims from providers who furnish ordered or referred items or services whose claims identify ordering or referring providers who do not have enrollment records in PECOS.

Response: Section 6405 of the Affordable Care Act, which this final rule implements, does not address payment or nonpayment of claims from physicians or eligible professionals who are not enrolled in Medicare. However, we understand the concerns that the commenters raised about physicians being enrolled only in PECOS. Consequently, we modified the PECOS requirement and now will permit enrollment in Medicare. We believe that the modification of the PECOS requirement will reduce the likelihood that providers and suppliers will have claims denied that were ordered or certified by a physician without a valid record in PECOS. Generally, physicians who are not enrolled in Medicare would not have their claims paid. However, this final rule deals only with the requirement that services or supplies provided by rendering/billing providers and suppliers must have been ordered or referred by a provider or supplier with an approved enrollment record in Medicare or the provider or supplier must have validly opted-out of Medicare. Therefore, the commenter's phased-in approach would not work within the context of this rule. However,

Medicare has developed a simplified enrollment process (form CMS-855O) for those who want to enroll in Medicare solely for the purpose of ordering and certifying.

Comment: A commenter stated that the inability of a provider or supplier to identify the correct teaching physician could cause that provider or supplier to choose not to submit a claim for a medically necessary item or service that is already furnished, meaning the provider or supplier would not receive payment to which it is entitled.

Response: We understand that the implementation of new policy requires providers and suppliers to adapt their processes. To assist in this effort, we have modified the provision in this final rule to permit individuals who are enrolled in an accredited graduate medical education program in a State that licenses or otherwise enables such individuals to practice or order and certify services, to enroll in Medicare to order and certify. In situations where States do not license or otherwise permit such individuals to practice or order and certify services, the teaching physician's full legal name and NPI must be included on the claim for services. In this last circumstance, the claim will not be paid unless the ordering and certifying physician, in this case, the teaching physician, is listed on the claim as the ordering or certifying physician.

Comment: Some commenters stated that CMS should sanction or otherwise penalize physicians who do not comply with the request to establish enrollment records in PECOS but who order or refer and cause the claims of other suppliers and providers to fail the ordering or referring provider edits and be rejected by Medicare. Another commenter asked that CMS modify this regulation by stating that beneficiaries and/or DMEPOS suppliers who were adversely affected by a physician's non-compliance should be able to initiate a complaint against the physician and submit evidence in support of the complaint.

Response: As stated previously, in light of our decision to modify the requirement that the ordering or referring providers must have enrollment records in PECOS, we believe the likelihood of claims being denied is greatly reduced because those physicians and eligible professionals in our legacy systems have been able to order and refer during the revalidation process. Further, we will not turn on the ordering and certifying automated edits that will cause a claim not to be paid for the lack of an enrollment record until those entitled to order and certify have

been notified of their need to revalidate. We have been working with suppliers, providers, and beneficiaries to educate them about the requirements of enrollment for ordering and certifying.

The provider or supplier can avoid a situation like the one described by the commenters by ensuring—prior to furnishing the service or item in question—that the physician is enrolled. The relationship that the commenters describe is between the physician and the provider or supplier whose claims were denied. We cannot serve as an intermediary in whatever dispute may arise between these parties concerning the physician's failure to be enrolled. The matter must be resolved between the parties themselves.

Comment: A commenter stated that it could potentially lose referral sources if it does not provide the services referred by physicians who do not have enrollment records in PECOS.

Response: As stated previously, we have changed the enrollment requirement from one mandating enrollment in PECOS to one requiring enrollment in Medicare—including PECOS or other Medicare systems. We believe this modification will largely alleviate the problem raised by the commenter. We will continue to engage in provider and supplier outreach and education on this issue. The Affordable Care Act imposed the ordering and referring requirement in section 6405 and we hope that physicians and eligible professionals will enroll in the interest of being able to order and certify items and services for their Medicare patients. As previously stated, we encourage rendering providers and suppliers to verify the ordering or certifying practitioners' enrollment status prior to rendering services.

Comment: A commenter noted that all of the services furnished by hospital-based radiologists are referred and that they have no way, within the short time frame between publication of the IFC and July 6, 2010, to inform and verify that referring providers have records in PECOS. Commenters also stated that because the billing provider will not be paid if the referring provider is not in PECOS, there will be a huge reduction in payments, resulting in the possibility of missing filing deadlines with insurance plans, and the patient will not be protected, and hospital-based radiology medical groups will have no income, no payroll, and no ability to maintain services for patients.

Response: Due to the comments received, we are removing the ordering or referring provider requirements on claims for physician specialists' services. In-hospital services that are

covered by the hospital inpatient prospective payment system (IPPS) payments will also not be subject to the requirements of this rule. However, in-hospital diagnostic testing services that are not paid as part of PPS (for example, imaging services furnished by an IDTF or another entity) must be ordered by Medicare enrolled providers. We have further clarified that we will provide ample notice to these providers when we decide to activate the edits that will cause a claim not to be paid for the lack of an approved enrollment record in Medicare or valid opt-out record in Medicare.

Comment: Commenters were concerned because pharmacies are required by law to include the name of the prescriber in prescriptions. Commenters described the administrative difficulties that would be present in trying to link a resident to his/her teaching physician in order to comply with the stated requirements in the IFC and the issues with respect to pharmacies that need to record, by law, the actual prescriber, who could be a resident. A commenter stated that not all pharmacy systems may allow the use of more than one identifier in a claim which would be necessary if a resident or intern ordered the item and the teaching physician needs to be identified as the ordering or referring provider. The commenter asked that CMS clarify the logistics and processes for pharmacists and pharmacy systems to identify, verify, and submit claims for intern/resident-generated orders and to identify teaching physician information. A commenter stated that because interns and residents move frequently among rotations, it will be difficult if not impossible for the pharmacies to contact the interns and residents in order to obtain the identity of the teaching physician.

Response: Neither the IFC, nor this final rule places requirements on prescribers identified in claims for drugs. As noted in the IFC, the ordering requirement in this final rule does not apply to Part B or D drugs.

Comment: A commenter stated that CMS should thoroughly consider the implications of new policies such as the ordering or referring provider edits before public release in order to thoroughly identify potential pitfalls beforehand.

Response: We agree with the commenter and have been sharing information with the public about these issues since 2009. In addition, the IFC published May 2010 offered an opportunity to comment on all aspects of the Affordable Care Act requirements. We believe it is important to continue

this kind of communication with the public and will continue to do so. Moreover, we will provide advance notice of the activation of the automated edits pertaining to these claims.

Comment: Commenters stated that nonprofit home health providers will be financially vulnerable because their core mission is to serve all patients regardless of their ability to pay. These commenters stated that nonprofit home health agencies have limited budgets and limited information technology (IT) support and personnel resources; thus, they are unable to quickly compare individuals in the Ordering Referring Report with their own list of ordering physicians or quickly disseminate the PECOS requirement to the physicians who order home health services from them. The commenters further stated that there is inadequate time for nonprofit home health agencies to learn about and efficiently use the “complex PECOS.”

Response: In order to do business with Medicare, all home health agencies, whether or not they are nonprofit, must submit claims that comply with our regulations in order to be paid for the home health services they provide. We believe the commenter is referring to Internet-based PECOS in using the term “the complex PECOS.” We make available at no charge the names and NPIs of those who are permitted to order and certify, who have approved enrollment records in PECOS, and who have validly opted out of the Medicare program. Also, a home health agency can and should ask the ordering/certifying physicians if they are enrolled in Medicare or have opted out of Medicare prior to accepting the order and/or certification.

Comment: Some commenters stated that home health agencies stand to suffer severe financial hardships because of reduced patient admissions and the costs associated with issuing Advanced Beneficiary Notices of Noncoverage (ABNs), causing patient dissatisfaction, which is long-lasting and rebuilding the relationship can take years.

Response: We understand these concerns. However, after consideration of our program integrity needs and the statutory mandate to implement this provision, we are moving forward with this final rule.

Comment: A commenter asked that CMS share the impact of this regulation on all areas of practice—the physicians who order home health, the HHAs, and the patients.

Response: We have interpreted this comment to suggest that we should educate these distinct communities on

how this rule will impact them individually. As stated previously, we will continue to provide additional information, education, resources, and guidance on this final rule across the spectrum of affected parties.

j. Claims Submission and Edits

Comment: Several commenters requested an explanation of potential future claim edits for over-ordering and over-referring items of home health and DMEPOS. The commenters were unaware of any statutory basis for such edits except to identify violations of the Stark law. Another commenter stated CMS should be required to state how it determines whether services are being “over-ordered.”

Response: The commenters are referring to a statement on the middle of page 24444 of the IFC which stated that based on the new NPI requirements, “

* * * if appropriate, we could establish edits to check for over-ordering specific items or services * * *” We have removed all references to these edits in the final rule. However, we will continue to utilize our oversight functions that do not involve edits, to monitor statistically anomalous ordering, certifying, and/or billing patterns and investigate when appropriate.

Comment: A commenter asked what is meant by the date of the written order or certification. The commenter asked if it is the date the referral or order was verbally received from the physician, or the date the physician signed the order.

Response: The language in the IFC used the term “date of written order or certification.” We intended that term to mean the date the physician signed the order or certification. Public comment indicated that often times written orders are signed well after the service is provided. We intended to mandate that the ordering and/or certifying practitioner be enrolled at the time the service is performed. Therefore, in response to public comment and for the purposes of this final rule, we have changed our terminology and will use the “date of service”, not the date of written orders or certifications. This change fully captures the purpose of this rule. Additionally, the date of service is much more accurate for claims and record retention purposes.

Comment: A commenter asked if the ordering and referring requirements for the Part B services mentioned in the IFC apply to such services when furnished in hospitals and billed using the Uniform Bill (UB-04). Another commenter asked if the IFC applied to Part A providers, such as hospitals or other entities, such as IDTFs and

freestanding imaging centers which provide services paid under Part B (submitted on the UB-04 claim form).

Response: The requirements in this final rule are applicable to the following ordered or certified items and services billed to Medicare by Part B suppliers of DMEPOS, clinical laboratory and imaging services, and for Part A and Part B home health claims:

- Part A and Part B home health services, submitted in claims from home health agencies to the Part A claims system at fiscal intermediaries and A/B MACs in ANSI X12N 837I or UB-94 formats.

- Part B clinical laboratory services, submitted in claims from independent clinical laboratories to the Part B claims system at carriers and A/B MACs in ANSI X12N 837P or CMS-1500 formats.

- Part B imaging services, submitted in claims from independent diagnostic testing facilities, portable X-ray suppliers, mammography centers, and radiation therapy centers to the Part B claims system at carriers and A/B MACs in ANSI X12N 837P or CMS-1500 formats.

- Part B items of DMEPOS, submitted by DMEPOS suppliers to DME MACs in ANSI X12N 837P, or CMS-1500 formats.

The requirements of this final rule are applicable to the following ordered items billed to Medicare by Medicare beneficiaries:

- Part B clinical laboratory services.
- Part B imaging services.
- Part B items of DMEPOS.

With the exception of claims for home health services that are submitted by home health agencies, this final rule does not affect the following:

- Claims submitted to the Part A claims system at fiscal intermediaries and A/B MACs.

- Claims for drugs.
- Part B claims from physician specialists.

- Claims from beneficiaries for home health services (beneficiaries are not permitted to submit claims for those services).

Comment: Two commenters were concerned that the ordering and referring provider edits on Medicare DMEPOS claims are not item-specific and that there are limitations in the claims processing system which may result in Medicare claims for Part B drugs being denied if the prescribers do not have approved enrollment records or valid opt-out records in PECOS. Specifically, the commenters stated that claims that are submitted in the National Council for the Prescription Drug Programs (NCPDP) 1.1 batch format are not subject to the ordering

and referring provider edits, whereas claims submitted using the allowable ANSI X12N 837P format are subject to the ordering and referring provider edits. The commenter also stated that because the claims are not edited based on the items in the claim, Medicare will reject claims for Part B DMEPOS drugs if the physician who prescribed the Part B DMEPOS drugs does not have an enrollment record in PECOS. The commenter is asking that Medicare not edit the ordering and referring provider (the prescriber) of Part B drugs regardless of which claim format is used.

Response: This final rule does not change the allowances permitted under HIPAA that allow retail pharmacies to submit claims on either the NCPDP format or the 837P format. However, as the commenter correctly points out, claims submitted in the NCPDP standard formats are not subject to the ordering and referring provider edits at this time. If an ANSI X12N 837P claim format is used to report drugs and DMEPOS and there is no EY modifier on the claim or if the claim reports only drugs and no EY modifier on the claim, the claim will be subject to the ordering and referring requirements of this rule. An EY modifier is a specific designation in the 837P format when, for example, the pharmacy knows the claim will be denied so that it may then use the Medicare denial for filing with secondary insurances that may allow for the payment of the item or service. We acknowledge that we will need to adjust claims payment processing to accommodate this rule. We are working towards making these necessary changes. However, in the interim, retail pharmacy claims that combine Part B drugs and DMEPOS supplies may be submitted using the NCPDP format to avoid this situation.

Comment: A commenter indicated that pharmacies that are also DMEPOS suppliers may submit and be reimbursed for claims for ordered or referred items after receiving an indication from the ordering physician that he/she has an enrollment record in PECOS. If it is later determined that the physician did not have an enrollment record in PECOS, will the pharmacy be liable or at risk?

Response: As noted in earlier responses, the Affordable Care Act requires that physicians who order certain items or services must be enrolled in Medicare. It is the billing provider or supplier's responsibility to ensure that the ordering or certifying physician or eligible professional has a valid enrollment record or has validly opted out. We have mentioned

numerous ways billing providers and suppliers can ensure compliance with this rule.

Comment: A commenter asked that pharmacies be provided with the normal Part B timely filing period in order to re-submit claims that fail the requirements of this regulation. The commenter then asks that pharmacies have 1 year in which to re-bill if the failure of the claim to pass the edits was beyond the control of a pharmacy. Another commenter asked that CMS permit suppliers to re-bill claims that were denied for PECOS edits for up to 1 year, and not apply the truncated 120 days normally provided for denied claims. Another commenter stated that when a DMEPOS supplier claim would be rejected for failing to meet the edit that the ordering or referring provider have an enrollment record in PECOS, it would fail a "front end" edit. Failing a front end edit means that the claim does not go to a DME Medicare Administrative Contractor (MAC) for adjudication. As a result, neither a remittance advice nor a Medicare Summary Notice would be produced, and appeal rights are not offered with proof that the ordering or referring provider is currently a Medicare provider. The commenter requested that the regulation be changed to allow (1) beneficiary liability using a proper ABN taking into consideration certain factors; (2) the claim to be processed beyond the "front end" so that the claim can be returned as unprocessable, which could enable the beneficiary community to prompt their physicians or other eligible professionals to establish their enrollment records in PECOS; or (3) deny (not reject) the claim using Adjustment Reason Code 52: "The referring/prescribing/rendering provider is not eligible to refer/prescribe/order/perform the service billed."

Response: Unless specified otherwise, in addressing these comments we are assuming that the commenters are referring to DMEPOS claims. This rule does not change any of the existing requirements for the resubmission of claims for payment. Although the IFC stated that we would reject, not deny, claims from providers and suppliers that do not comply with the requirements that those who order and refer services or supplies must be enrolled in Medicare or validly opt out, we have determined in this final rule that we will deny such claims. As stated in previous responses, we have not yet activated the automated edits that would cause a claim not to be paid because a physician or, where applicable, eligible professional who ordered or certified the service does not

have an approved enrollment record in Medicare, and we will provide ample notice prior to activating the edits. However, the resubmission and payment of a claim by pharmacies would not be possible under the commenter's scenario because the physician or eligible professional was not enrolled in Medicare or did not have a valid opt-out record on the date of service.

Comment: Many commenters requested that CMS generate more meaningful explanations as to why claims failed the ordering and referring provider edits. For example, they want to know if the rejection codes will be different for claims that fail the ordering and referring supplier edits because the ordering or referring supplier is a physician or other eligible professional but does not have an enrollment record in PECOS and claims that fail the ordering or referring supplier edits because the ordering or referring supplier is not a physician or other eligible professional.

Response: We agree with these comments and we are in the process of developing more descriptive informational messages. We will provide new informational messages that provide these details and will describe these new messages to the provider and supplier communities in a Medicare Learning Network article shortly after publication of this final rule.

Comment: A commenter stated that Medicare beneficiaries are limited to the submission of one DMEPOS claim per lifetime. The commenter, therefore, requests that a beneficiary-submitted claim for DMEPOS items be rejected, not denied, if it fails the edits, in order to avoid "wasting" the once-per-lifetime claim benefit.

Response: The permissive, once-in-a-beneficiary's-lifetime, payment of a beneficiary-submitted claim for an item of DME, or of a Medicare-covered supply, is intended to apply only to incidental items that a beneficiary might obtain from an entity that a beneficiary might reasonably assume was enrolled in Medicare but was, in fact, not so enrolled. This limited exception to the general rule furnishes notice to the beneficiary of the supplier enrollment requirement (and the beneficiary's duty to inquire of the supplier's Medicare enrollment status in the future), while holding the beneficiary harmless for his or her ignorance of the rule, this single time. Beneficiaries are able to submit claims from enrolled Medicare suppliers as is necessary, and are not in danger of "wasting" the once in a lifetime benefit under this final rule.

Regardless of the applicability of the comment, claims from beneficiaries will be denied, not rejected, to afford them appeals rights. Under Medicare, a claim is rejected when the claim filing has a defect or impropriety such that it cannot be processed. A claim that was ordered by a non-enrolled physician or eligible professional is a claim where a required element of the furnishing of the item to the beneficiary does not meet Medicare requirements, and it must be denied, not rejected.

Comment: Many commenters stated that home health agency providers would have to discharge many home health patients because the IFC requirement that certifying physicians have enrollment records in PECOS by July 6, 2010 could not be met. The commenter stated that home health patients would then end up in hospitals or other acute facilities. The commenters wanted such home health agencies to be held harmless from claim denials if they submitted claims for their services in order to avoid putting beneficiaries into this situation.

Response: While efforts were underway to enroll physicians and eligible professionals who order and refer prior to the passage of the Affordable Care Act, the implementation date is statutorily mandated. We conducted significant outreach on this effort and will continue to do so when implementing this final rule. As already stated, we have taken steps to help mitigate these circumstances; for instance, we have not yet activated the automated edits that would cause claims for services or supplies not to be paid for lack of an approved enrollment record in Medicare. Consequently, we do not believe it is necessary to hold home health agencies harmless if the ordering/certifying provider reported in their claims is not enrolled in Medicare in an approved status or has not validly opted out of Medicare.

Comment: Several commenters wanted assurance that home health agencies would not face a retroactive recovery based on the application of the "without fault" provision if they submitted claims in good faith, believing that the physician had an approved enrollment record in PECOS or had attempted to enroll in the Medicare program before submitting the claim. They did not want the provision of home health services to patients whose physicians do not have enrollment records in PECOS to be considered a violation of any Medicare rule if the home health agency has documented its efforts to determine if

the physician has an enrollment record in PECOS.

Response: The "without fault" provision under section 1870 of the Act is not applicable in this scenario, as that provision refers to the collection of overpayments. The billing provider has an affirmative responsibility under this final rule to ensure that the physician has a valid enrollment record or has validly opted-out. Additionally, records for the orders and certification of home health must be maintained by the ordering/certifying physician(s) and the home health agency that bills for these services. Submitting a claim in good faith does not meet our requirements and will be denied if the ordering/certifying physicians do not have a valid enrollment or opt-out record. We note that home health payment is always contingent on whether eligibility requirements, including the requirement that a patient be under the care of a physician, continue to be met. Typically, "under the care of a physician" would require active physician involvement with updating orders. It is difficult to envision a scenario where the patient could be under the care of physician unless that physician is able to order services. As such, as part of our eligibility requirements, the patient must be under the care of a Medicare enrolled physician, because only an enrolled physician can order home health services. HHAs are responsible for coordinating patient care, as defined in Conditions of Participation defined in 42 CFR Part 484. They are also responsible for ensuring that all eligibility criteria, such as the need for a patient being under the care of a physician, are met.

Additionally, we have modified the definition of "enrolled in Medicare" to include PECOS and existing legacy Medicare claims payment systems. We have also delayed the automated edits that will cause a claim not to be paid for the lack of an approved enrollment record in Medicare or a valid opt-out status. Of course, such claims are subject to all other Medicare requirements, such as, coverage and medical necessity. These changes will reduce the risk to home health suppliers of having claims denied on the basis of enrollment of the ordering or certifying physician. We have made the Ordering Referring Report, containing the NPIs and legal names of physicians and other eligible professionals who have approved enrollment or valid opt-out records in PECOS, available and are encouraging suppliers to view this report. However, documentation that a home health agency has done so does

not fulfill the requirements of this final rule. We also make available four reports within the Ordering Referring Report that include the following:

- Physicians who are approved to order and refer.
- Other eligible professionals who are approved to order and refer.
- Physicians who have pending Medicare enrollment applications.
- Other eligible professionals who have pending Medicare enrollment applications.

These reports, collectively referred to as the Ordering Referring Report, are available on the Medicare provider/supplier enrollment Web page at (www.cms.gov/MedicareProviderSupEnroll). This information makes it easier for home health agencies to determine the enrollment or opt-out status of physicians who have ordered home health services prior to submitting their claims.

Comment: A commenter indicated that while home health agencies would attempt to secure the NPI of the ordering or referring provider and report that NPI in claims, the information needed to do so is not fully available and will not be provided by CMS in a manner that assures providers and suppliers access to the most up-to-date information when they are determining whether or not to accept a referral from a physician. Other commenters expressed concern that the requirement to report the NPIs of ordering and referring providers and suppliers in claims may penalize billing providers if the ordering or referring provider has not obtained an NPI or does not furnish the NPI to the billing provider, and that such a penalty would disadvantage otherwise compliant billing providers.

Response: If a home health agency provider or a supplier receives an order or a certification from a physician or other eligible professional and the NPI is not on the order or certification, the provider or supplier can ask the physician or other eligible professional to disclose his or her NPI. If that is not feasible, the provider or supplier can use the NPI Registry (<https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do>) to obtain the NPI. High-volume providers and suppliers may wish to download the NPPES file each month (http://nppes.viva-it.com/NPI_Files.html) and import it into its claims and/or business processes to pull the NPIs from it and use them in electronic processes. Ultimately, if a billing provider or supplier who furnishes items or services based on orders or certifications is unable to obtain this information from the

ordering and certifying provider, the billing provider should carefully consider, as part of its business policy, whether or not it will accept an order or a certification from a physician or other eligible professional who does not have, or who refuses to obtain, an NPI.

Comment: A few commenters questioned if a full episode of home health care would be paid if a physician terminates enrollment before the end of a 60-day home health episode.

Response: Yes, this regulation requires enrollment in Medicare or a valid opt-out status that would be assessed based upon the date of the order and the date of the certification, for dates of service beginning July 6, 2010. In the situation described by the commenter, Medicare would not deny payment (for the lack of an approved enrollment or opt-out record) for any portion of the full 60 days if the ordering physician were to terminate enrollment or otherwise become not enrolled in Medicare. However, Medicare may deny these claims based upon other factors unrelated to enrollment status of the ordering or certifying supplier.

Comment: A few commenters questioned if Medicare would pay a home health claim if the certifying physician does not have an approved enrollment record or a valid opt-out record in PECOS at the start of care, but does establish such a record during the course of the episode of care and prior to the submission of the claim from the home health agency.

Response: Consistent with the provisions of this final rule, the ordering/certifying physician(s) would have to be enrolled in Medicare in an approved status or have validly opted-out of the Medicare program as of the date of service in order for the home health agency's claim to be paid.

Comment: A few commenters questioned if the ordering and referring provider edit will be on the home health request for anticipated payment (RAP), final claim, or both. A few commenters questioned if a corrected RAP, final claim, or both could be submitted if a provider or supplier submitted an incorrect ordering or referring provider name and NPI in a claim but later learned the correct information.

Response: Home health episodes are paid in two pieces: A anticipated payment amount at the beginning of the 60-day episode, and the balance in the final claim at the end of the 60-day episode. The RAP is the first submission of the claim. Therefore, the ordering/certifying physician(s) must be in compliance with our regulations on the date of service (that is, the date of the

order or certification). A RAP cannot be adjusted once it has been processed, but it can be cancelled and resubmitted with corrected information including provider name or NPI. If a home health agency learned that data on a RAP was in error, the home health agency could cancel the RAP and resubmit it. This is also the case for the home health final claim. Therefore, the edit will apply to both the RAP and the final claim.

Comment: A commenter expressed concern that it is not always possible for a home health agency to know for certain at the start of care which physician will certify home care services. This commenter questions whether only PECOS enrolled physicians will be able to make referrals and certify home health episodes of care.

Response: In most cases the same physician would refer the patient to home health, order the home health services, certify the beneficiary's eligibility to receive Medicare home health services, and sign the Plan of Care. It is the NPI of the ordering/certifying physician that is required on the claim and in the medical record.

However, we recognize that in certain scenarios one physician may not perform all of these functions. An example of such a scenario would be a patient who is admitted to home health upon hospital discharge. While we would still expect that in most cases, a patient's primary care physician would be the physician who refers and orders home health services, certifies eligibility, and signs the plan of care, there are valid circumstances when this is not feasible for the post-acute patient. For example, some post-acute home health patients have no primary care physician. In other cases, the inpatient physician assumes primary responsibility for the patient's care during the acute stay, and may (or may not) follow the patient for a period of time post-acute. In circumstances such as these, it is not uncommon for the inpatient physician to refer a patient to home health, initiate orders and a Plan of Care, and certify the patient's eligibility for home health services. In the patient's hospital discharge plan, if the inpatient physician would not be the one to follow up for the duration of the home health service, he or she would identify the community physician who would be assuming primary care responsibility for the patient upon discharge. It would be appropriate for the physician who assumes responsibility for the patient to sign the plan of care. The patient would thus be considered "under the care" of that community/personal physician

throughout the time the patient is receiving home health services.

In a scenario such as this, if the inpatient physician certifies the patient's home health eligibility and initiates the orders for services, that physician would need to be a Medicare enrolled physician, and that physician's NPI would be in the medical record and on the first home health claim. To be compliant with all Medicare home health coverage and payment rules, the community physician who assumes responsibility for the patient during the home health episode (updating orders, signing the plan of care, etc.) would also need to be a Medicare enrolled provider, and this NPI would also be documented in the medical record and on the appropriate home health claim.

Comment: Given that the process by which home health care services are ordered and because the process used for such referrals (electronic, fax, telephone) almost never includes direct communication from a physician to a home health agency, a commenter suggested that Medicare require only that physicians who certify home health services be required to be enrolled in PECOS. This commenter also asked that claims that lack a PECOS-enrolled physician's NPI be rejected rather than denied.

Response: The statute specifically references orders and certifications for home health services. Therefore, we disagree that only the physician who certifies the home health services be required to be identified in the claim for home health services and meet the requirement to be enrolled in Medicare in an approved status or have validly opted out of Medicare. Claims from home health agencies that do not meet the requirement that the ordering/certifying physician be identified by legal name and NPI will be denied, not rejected, as noted earlier in this final rule.

Comment: Several commenters stated that beneficiary notification of nonpayment for home health services was not addressed in the IFC. The commenter noted that home health agencies are required to notify Medicare beneficiaries of noncoverage of all services through a Notice of Medicare Noncoverage (Expedited Determination Notice), and that home health agencies are required to notify patients of their right to appeal a noncoverage determination while continuing services if orders are in place from a physician through a Home Health Advance Beneficiary Notice (HHABN). The commenters believe that beneficiaries will be prevented from continuing to receive medically necessary services

under self-payment or other payment sources that are secondary to Medicare in cases where expedited appeal decisions are delayed or are not in the beneficiaries' favor. The commenters recommended that CMS permit the HHABN to be used when home health services are not covered because the order was written by a physician who does not have an enrollment record in PECOS.

Response: As the commenter stated, HHABNs are for notification of noncovered services. The home health services themselves are still considered "covered services" if they meet the Medicare medical necessity and benefit requirements, even if the ordering/certifying physician is not enrolled in, or opted out of, Medicare. However, the claim will be denied due to noncompliance with this regulation if the ordering/certifying physician is not enrolled in Medicare or does not have a valid opt-out status. The denial of a claim for lack of an approved enrollment records in Medicare is not a coverage determination; hence the HHABN is not applicable.

k. NPI Data and Requirements

Comment: A commenter asked how CMS would know that an NPI on a claim was put there by a physician who meant to order the test and not by someone who simply downloaded the NPI from the open file.

Response: Our systems are equipped to check for these types of compromised numbers and initiate an investigation based upon the data. While we understand the concerns of the commenter, verification of the NPI is just one tool we use to validate a claim. Access to NPIs and the associated names are crucial pieces of information to individuals providing services and supplies. Penalties for this type of activity can range from false claims liability to other criminal and civil sanctions. CMS and law enforcement actively monitor this type of activity and regularly engage in investigation and follow-up activities, as appropriate.

Comment: A commenter believed that the widespread dissemination of physicians' and other eligible professionals' NPIs could increase the risk of fraudulent use of NPIs and urged CMS to implement procedures to protect practitioners from any unreasonable additional compliance burden that may be incident to the misuse of their NPIs by others.

Response: Providers and suppliers must determine if the ordering and certifying physician or eligible professional is enrolled in Medicare at least to order and certify. Inclusion of

this information on the claim is necessary for the payment of claims. We must provide this information publicly so that service providers can ensure that physicians and eligible professionals are enrolled in Medicare to order and certify. If a health care provider suspects misuse of an NPI, that health care provider should report the issue to law enforcement authorities including, when appropriate, to the DHHS Office of Inspector General (OIG). The OIG Hotline is 1-800-HHS-TIPS (1-800-447-8477). Providers and suppliers can also report suspected misuse of an NPI to 1-800-Medicare.

Comment: Several commenters noted the following:

- There is no required OMB approved form for ordering home health services.
- The plan of care content requirements are based on the Home Health Content of Plan of Care.
- We have removed from our online manual the detailed guidance on the required Content of the Plan of Care.
- Inclusion of the physician's NPI on a Home Health Plan of Care and interim orders has never been a requirement.

Response: The Secretary has adopted a standard electronic referral transaction. However, most health plans have not implemented the adopted electronic referral standard and continue to use their own paper formats and issue their own instructions for the use of the paper referral formats. The absence of the Plan of Care guidance in the online manual does not impact the requirements of this final rule.

Regulation text at § 424.516 currently requires that the NPI of the physician who orders/certifies the home health services be part of the documentation of the service in the medical record. It does not stipulate that the NPI be included on the Plan of Care or certification. Content requirements for the Home Health Plan of Care are detailed in § 484.18(a). So long as the NPI is part of the medical record, and can be provided to CMS or a Medicare contractor upon request, the home health agency will have met this requirement.

l. Legal Name Requirements

Comment: A commenter sought clarification as to whether the IFC required that the provider of the service must also provide its legal name and NPI on the claim.

Response: We are interpreting this question as asking whether the IFC required the billing provider to list its NPI and legal name on the claim. The requirement for the billing or rendering provider to list its NPI was effective March 1, 2008. There is no requirement that the legal business name of the

billing provider be explicitly listed on the CMS-1500 claim form. Note that the IFC established a requirement that the eligible ordering and/or referring supplier's legal name be listed on the claim. Those requirements are now incorporated in § 424.506 (rendering or billing provider NPI on claims) and § 424.507 (ordering and certifying supplier NPI).

Comment: A commenter stated that ordering or referring suppliers do not always write their legal names on their prescriptions or orders, and thus it is a burden on the billing provider to do the research to determine the legal name so that it can be included on the claim.

Response: Providers and suppliers who furnish items and services based on orders or certifications should have business operations in place to ensure that they collect the information necessary to submit a proper claim for payment for those items and services. This would include collecting the legal name of the individual who ordered or certified these items or services.

Comment: A commenter stated that several medical practices have contacted CMS about the name of the ordering or referring supplier reported in their claim not matching CMS records, and were told that the name on the claim had to match the name in NPES. Several other commenters stated that the NPI of the ordering or referring provider should be sufficient to match PECOS records and that the legal name is unnecessary.

Response: The only name that should be used for an enrollment application or on a claim form should be the individual practitioner's legal name that matches the name and NPI of record from NPES. Those records match the practitioner's legal name from the Social Security Administration (SSA). The use of this name will ensure there is no confusion at the time of enrollment and claims processing.

Existing regulations and policies require the reporting of the legal name if the NPI is required to be reported. Requiring the name that corresponds to the NPI further ensures the validity of the ordering or certifying provider and eliminates the indiscriminate and repeated use of any valid NPI simply to enable a claim to pass an edit. The health care claim standard and the Medicare paper claims forms capture three fields for a name: last name, first name, and middle initial. The Medicare provider/supplier enrollment application also captures those same three name fields. For the purposes of this rule only, these three name fields (last name, first name, and middle

initial) constitute an individual's legal name.

Comment: Some commenters stated that CMS should eliminate the first name match because many systems reference a physician by a nickname; and only use the surname and NPI to match.

Response: As previously described, our rules require the full legal name (that is, first name, middle initial, and last name). Reporting a nickname in a Medicare enrollment application will likely cause that enrollment application to fail the social security number verification, which would delay the processing of the enrollment application or cause it to be rejected. Similarly, use of a nickname on claims will likely cause the claim to be denied.

Comment: Another commenter was concerned about name changes, resulting from marriage, in which a physician's surname in PECOS is no longer consistent with the married name being used in orders and referrals.

Response: Any enrolled Medicare provider and supplier whose name changes is required to report that change to the designated Medicare contractor within 90 days of the effective date of the change. Other appropriate files and systems are also updated with any new information.

m. Enrolling in Medicare Just to Order and Refer

Comment: A commenter stated that the PECOS enrollment system does not have flexibility to permit Department of Veterans Affairs (DVA) employed physicians to enroll. Another commenter stated that a representative of a Veterans Affairs hospital stated that their physicians who order and refer items and services for Medicare beneficiaries will not be enrolling in Medicare because they do not send claims to Medicare. Another commenter stated that CMS should develop a simplified enrollment process for dentists and others who do not submit claims to Medicare. Another commenter stated that physicians who care for patients in institutional settings will refer for home care and DMEPOS, as do physicians in training (residents and fellows) who are not eligible to enroll in Medicare. Several commenters suggested that CMS simplify the enrollment process for those who must enroll just to order and refer. Another commenter asked that DVA providers be excluded from the requirement to enroll in PECOS in order to continue to order and refer items and services for Medicare beneficiaries.

Response: We agree with the previous commenters regarding the development

of a simplified process for individuals who enroll just to order and certify. DVA and other professionals cannot be excluded from the enrollment requirement because the statute requires that those who order DMEPOS and who order/certify home health services be enrolled in Medicare. We have had numerous detailed discussions with DVA officials, as well as officials at the Department of Defense (DoD), the United States Public Health Service (PHS), Indian Health Service (IHS), and other Federal agencies whose physician employees order and certify Medicare services or supplies but do not bill Medicare directly.

We have developed the CMS-855O enrollment form for eligible providers and suppliers who wish to enroll only to order and certify. The ordering and certifying suppliers who use the CMS-855O form may not bill Medicare and submit claims. Those suppliers who wish to bill Medicare for services and submit claims must fill out the CMS-855I form. Internet-based PECOS has the capability to handle enrollment applications from these physicians and other eligible professionals who wish to enroll in Medicare just to order and certify. The CMS-855O form has been approved by Office of Management and Budget (OMB) and has been available for use since July 1, 2011. Additionally, information about enrolling only to order and certify is available on the Medicare provider/supplier enrollment Web site (<http://www.cms.gov/MedicareProviderSupEnroll>).

Examples of physicians and other eligible professionals who may wish to enroll in Medicare only to order and certify, and not to submit claims to Medicare for payment, include those who are one of the following:

- Employed by the PHS, DOD, DVA.
- Employed by Medicare-enrolled Federally qualified health centers (FQHCs), rural health clinics (RHCs), and critical access hospitals (CAHs).
- Pediatricians who traditionally have very few Medicare patients and, therefore, only order or certify items for Medicare beneficiaries.
- Doctors of dental medicine or dental surgery whose services are generally not covered by Medicare.
- Residents, as defined in § 413.75 (to include interns and fellows), who are appointed by teaching hospitals and academic medical centers who generally do not enroll in Medicare because their services are not directly billed to Medicare. (Please see the information under the "residents" section of this final rule.)

Comment: A few commenters stated that officials at DVA facilities stated

they were unaware that their physicians needed to enroll in Medicare. Some commenters stated that DVA physicians have told them that they cannot enroll in Medicare until ordered to do so by the DVA.

Response: We have communicated with the DVA and expect that their physicians and other eligible professionals will enroll in Medicare just to order and certify if they wish to continue to order or certify items or services for Medicare beneficiaries.

Comment: Several commenters stated that CMS should consider how best to communicate with physician practices, including those in the PHS, DoD, and DVA, as well as dental and pediatric practice settings and teaching physicians and those who have opted out of Medicare to ensure they understand the new requirements.

Response: We have been in communication with the PHS, DoD, DVA, and the American Dental Association (ADA) about the requirements of the Affordable Care Act that we are implementing with this final rule. We anticipate additional communication in CMS provider/supplier open door forums and in our regular conference calls with national provider/supplier associations and organizations. We will be creating additional outreach documents when we publish this final rule. Largely based on provider and supplier concerns and in an effort to accommodate these concerns we have created a new enrollment form, the CMS-855O. This form is specifically designed for those providers and suppliers who want to enroll in Medicare for the purpose of ordering and certifying only. We believe this shortened form will streamline the enrollment process, especially for this segment of the supplier communities.

Comment: A commenter suggested that there should be a longer phase-in time for dentists and other eligible professionals who rarely refer or order under Medicare.

Response: We have created a streamlined application process that reduces the time it will take for dentists and other professionals to enroll, since they generally do not bill Medicare but who need to enroll in Medicare just to order and certify. The CMS-855O may be used by providers and suppliers who simply wish to order and certify and who do not wish to submit claims to Medicare. These changes, including the new CMS-855O enrollment form, the change from the requirement to be enrolled in PECOS to a requirement to be enrolled in Medicare, and the delay in the activation of the automated edits that would cause a claim to not be paid

due to lack of an approved enrollment record in Medicare, have simplified compliance for these types of professionals.

n. Interns, Residents, Fellows, and Teaching Physicians

Comment: A commenter supported the requirement that interns who are not licensed, and therefore unable to enroll in Medicare should order or refer through the teaching physician. The same commenter also asked that CMS allow licensed residents to order or refer under their own name (not the name of the teaching physician) to avoid artificially increasing the ordering or referring patterns of teaching physicians. The commenter did not believe this would have a negative impact on the Medicare program and would still enable CMS to track ordered and referred items and services. Another commenter stated that many residents are licensed physicians who are qualified to practice independently and who are undergoing specialty training. The commenter believed that these residents should not be limited in their ability to order and refer because of perceived shortcomings with PECOS's ability to accommodate them.

Response: Physicians and eligible professionals must have an appropriate State license in order to enroll in Medicare, and licensure is determined by State laws. Based on provisions included in this final rule, physicians and other eligible professionals who order/certify DMEPOS, home health services, clinical laboratory, and imaging services for Medicare beneficiaries must be enrolled in Medicare or have validly opted out. The term "resident" is defined in § 413.75 as " * * * an intern, resident, or fellow who participates in an approved medical residency program, including programs in osteopathy, dentistry, and podiatry, as required in order to become certified by the appropriate specialty board." Licensed residents, as defined in § 413.75, usually do not enroll in Medicare because they do not bill the Medicare program; their services are included in the hospitals' PPS claims and Medicare reimburses the hospitals. We agree with the concerns expressed by commenters and have modified the requirements of this final rule so that if States allow residents who have a provisional license, or are otherwise permitted by State law to practice or order and certify services, we will permit them to enroll in Medicare to order and certify, at the direction of their teaching institution. In situations where States do not offer licensure or otherwise permit such individuals to

practice or order and certify services, the teaching physician's legal name and NPI must be included on the claim for services. In this latter circumstance, the claims will not be paid unless the ordering and certifying physician, in this case, the teaching physician, is listed on the claim as the ordering or certifying physician.

Comment: Some commenters expressed concern about the amount of resources that would be required by hospitals and academic medical centers to enroll licensed residents and fellows so that they may continue to order and certify. A commenter stated that a hospital-wide process must be developed for residents to note their supervising physician on orders, which adds a significant layer of complexity to hospital operations. Another commenter believed that reporting the teaching physician's name and NPI as the ordering or referring supplier when a resident or intern orders or refers sounds like a practical solution, but the administrative burden placed on teaching hospitals to ensure a proper link between a resident and a teaching physician in order to submit these claims is a huge cultural and administrative paradigm switch that will take time to develop, communicate, and put into operation.

Response: As stated previously, in order to comply with the requirements of section 6405 of the Affordable Care Act, a Medicare-enrolled physician must be identified for orders or certifications for items and services that will be billed to Medicare. As stated in the previous response, we have modified the final rule to accommodate teaching hospitals by providing them the option of either enrolling individuals enrolled in an accredited graduate medical education program (when State law permits) or by identifying the teaching physician in the claim. We have developed these options in an effort to avoid disruption of existing practices in teaching institutions as much as possible.

Comment: A commenter stated that physicians in training work in a cost-efficient fashion under the supervision of attending physicians and that to require that every order in a large teaching service be written by an enrolled physician (an attending physician) or a mid-level practitioner will place a considerable financial burden on teaching hospitals and medical schools, many of which are struggling financially. The commenter stated that these facilities would need to have a large cadre of Medicare-enrolled physicians or mid-level providers available at all hours, and that this

requirement will dilute the training experience of resident physicians because they will be unable to independently order even the simplest diagnostic test.

Another commenter believed that the requirements will make it virtually impossible for resident physicians and fellows to order diagnostic procedures, testing, and consults for Medicare beneficiaries. Residents and fellows who are reasonably well supervised will deliver less costly care than poorly trained residents. The commenter contended that those who have never had to think independently will become very costly suppliers because they will try to compensate for their lack of clinical judgment with over-testing.

Response: We believe that the modifications we made to the final rule should diminish the concerns of the commenter. As stated previously, we have provided options for the teaching hospitals to enroll individuals in an accredited graduate medical education program in Medicare if permitted by State law or regulation.

Comment: Several commenters stated that residents who are licensed physicians should be allowed to enroll in Medicare and order home health services.

Response: Licensed residents are physicians and, as such, are eligible to enroll in Medicare. Medicare regulations state that only physicians who are doctors of medicine, osteopathy, or podiatry may certify home health services.

Comment: Several commenters stated that CMS should consider categorizing fellows who do not bill Medicare to be “residents” so that the teaching physicians would be reported in the claim as the ordering or referring provider. By doing so, the Medicare contractors would have fewer enrollment applications to have to process, which could help reduce their workload.

Response: We agree with the commenters’ suggestion and have modified this final rule to permit individuals who are enrolled in an accredited graduate medical education program in a State that licenses or otherwise enables such individuals to practice or order and certify services to enroll in Medicare to order and certify. In situations where States do not license or otherwise permit such individuals to practice or order and certify services, the teaching physician’s full legal name and NPI must be included on the claim for services. In this latter circumstance, the claims will not be paid unless the ordering and certifying physician, in this case, the teaching physician, is

listed on the claim as the ordering or certifying physician. Therefore, recategorizing fellows is unnecessary and we defer to State scope of practice laws and regulations on who may order and certify.

Comment: A commenter suggested that CMS allow residents to enroll and to be identified in PECOS as residents. Teaching hospitals could enroll their residents using a new code to reflect this status. Because this would take some time to implement, the commenter suggested that CMS further delay (beyond the commenter’s suggested implementation date of January 3, 2011) the requirement that ordering or referring providers have enrollment records in PECOS.

Response: The applicable statutory and regulatory provisions do not permit Medicare to enroll an unlicensed physician. However, if States provide provisional licenses or otherwise permit residents to practice or order and certify services, we are allowing them to enroll to order and certify, consistent with State law. Further, the timing of licensure of a resident is determined by States and because we are now permitting licensed residents to enroll in Medicare, it is not necessary and may be duplicative, to develop an additional code in the enrollment systems.

Comment: Commenters stated that it would be extremely difficult for teaching hospitals to comply with the July 6, 2010 date because of its timing with the start of the new academic year. Teaching hospitals are focused on activities regarding the turnover of what is often 25 percent of their residents and there is no time to suddenly add a new and disruptive component to those ongoing activities. They express concern about ensuring that their graduates are prepared to practice or continue with additional training and that the new residents are appropriately credentialed so they can begin their training on July 1, 2010.

Response: We have been working closely with these institutions to ensure effective compliance with our regulations by the statutorily mandated effective date. We clarified in this final rule the circumstances under which individuals enrolled in accredited graduate medical education programs can enroll in Medicare to order or certify Medicare services. Those residents, as defined in § 413.75, who are licensed may enroll in Medicare to order and certify in the same way other as physicians and other eligible professionals. This final rule states that if State law provides residents, as defined in § 413.75, a provisional license, or otherwise permits them to

practice or order and certify services, we will enroll them to order and certify. If State law does not provide licensure for residents, or otherwise permit them to practice or order and certify services, claims for services provided must identify the teaching physician as the ordering or certifying physician by his or her legal name and NPI. This modification from the IFC will provide these teaching institutions with options to accommodate the policies mandated by the Affordable Care Act and this final rule.

o. Deactivation

Comment: Many commenters noted that physicians and other eligible professionals who will enroll just to order and refer and not to submit claims to Medicare will be deactivated if they fail to send claims to Medicare for 12 consecutive months, and that after deactivation, they would then need to re-enroll in order to continue to order and refer. Some of the commenters indicated that § 424.540 states that CMS “may” deactivate the enrollment of a provider or supplier if no claim is submitted for a year. They suggest that the use of “may,” gives CMS discretion. These commenters suggested that CMS use this discretion and exempt from this deactivation process dentists and others who would be enrolling just to order and refer.

Response: Deactivation for non-billing does not apply to those physicians and eligible professionals who have enrolled just to order and certify.

Comment: A commenter asked that CMS terminate NPIs, not Medicare-assigned PTANs, when a physician’s billing privileges are deactivated. The commenter pointed out that a physician may have multiple PTANs in his/her PECOS enrollment record, and that if one PTAN is deactivated voluntarily or due to non-billing, that physician is no longer eligible to order and refer although the physician is still enrolled in Medicare and is still sending claims with, or being identified in claims as the rendering provider by his/her NPI. The commenter suggested that the NPI, not the PTAN, should be the driver of ordering and referring eligibility.

Response: The commenter is correct that a physician can have multiple PTANs and currently deactivation for non-billing is driven by PTAN rather than NPI. More than one PTAN may be assigned to a physician if the physician reassigns his Medicare benefits to more than one medical group (a PTAN for each reassignment), or works at multiple/different practice locations (a PTAN for each practice location). Any provider or supplier, including a

physician, whose billing privileges are deactivated for 12 consecutive months of non-billing is deactivated by his or her PTAN. However, the deactivation of one PTAN does not deactivate all PTANs. If the physician or other eligible professional has more than one PTAN, and not all PTANs were deactivated due to non-billing, he or she will remain enrolled in Medicare to bill using the active PTANs and will also remain on the Ordering Referring Report. In this situation, claims in which he or she is identified as the ordering and referring provider would not be denied because of one deactivated PTAN.

p. Validly Opting Out

Comment: A few commenters stated that Medicare contractors do not enter opt-out physicians in PECOS. Another commenter stated that opt-out physicians have records in PECOS only in situations where they were first enrolled in Medicare and then opted out.

Response: Based on the Affordable Care Act provisions requiring that ordering and referring physicians must be enrolled in Medicare, we have instituted a consistent process for entering physicians who opt out into PECOS. When processing an opt-out affidavit, Medicare contractors may require, and the opting out physician or other practitioner must provide, the NPI as well as other information that may be requested by the Medicare contractor. Physicians and other practitioners do not have to enroll in Medicare before opting out. Those who opt out must submit opt-out affidavits every 2 years and all who have opted out of Medicare will have opt-out records in PECOS.

Beneficiaries and other providers and suppliers may visit the Physician Compare Web site at <http://www.medicare.gov/find-a-doctor/provider-search.aspx> to see if their physicians or other practitioners are enrolled in Medicare. If the beneficiary's physician or other practitioner is not enrolled in Medicare and has not opted out, the beneficiary may wish to find another physician or practitioner. For more information on opting out of Medicare, the public may refer to our applicable regulations at § 405.425, titled "Effects of opting-out of Medicare."

Comment: Some commenters requested that CMS make available a list of physicians and other eligible professionals who have opted out of Medicare.

Response: Physicians and other practitioners who have validly opted out of the Medicare program have opt-out records in PECOS. Physicians and

non physician practitioners who have validly opted out of the Medicare program, and elect to order and certify, will be on the Ordering Referring Report. The Ordering Referring Report does not distinguish those who have opted out from those who have approved enrollment records because both, if listed in the Ordering Referring Report, may order and certify items and services for Medicare beneficiaries.

q. Public Comments Outside the Scope of the IFC Provisions Regarding Ordering and Referring Covered Items and Services

Comment: A commenter noted that the preamble in the IFC states that CMS believes its enrollment requirements will promote quality health care services for Medicare beneficiaries because their credentials will have been verified as part of the Medicare enrollment process. The commenter states that physicians' credentials have already been verified by State licensure boards. The commenter believes that additional verification by Medicare is redundant and a waste of taxpayers' money and professionals' time.

Response: While we believe that additional verification is necessary to ensure quality care is provided to Medicare beneficiaries, this comment is outside of the scope of this final rule. This rule does not modify or impose additional screening requirements needed for enrollment in Medicare.

Comment: A commenter stated that dentists, who merely order and refer, may be further burdened if they will be required, as a condition of enrollment, to establish a compliance plan.

Response: Neither the IFC nor this final rule addresses the issue of "compliance plans." This comment is out of scope of this regulation. We solicited comments related to compliance plans in the September 23, 2010 proposed rule (75 FR 58204) titled "Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers."

Comment: A commenter who supports the new requirement to be enrolled in Medicare to order and refer suggested that CMS develop a program that rewards physicians for making appropriate referrals to the lowest cost providers as a good second step in cost containment. The commenter noted that there is no incentive for a physician to consider costs in the referral process.

Response: This comment is outside the scope of this regulation and, as such, is not addressed in this final rule.

Comment: A commenter referenced the professionals listed in the IFC who are permitted to order and refer covered Part B DMEPOS, imaging, laboratory, and specialist items/services and stated that certified registered nurse anesthetists (CRNAs) should be eligible to order and refer some of those items and services. The commenter stated that CRNAs order blood work and electrocardiograms as part of the pre-anesthetic assessment, order medications for the purpose of administering them perioperatively, and also have occasion to order chest X-rays for patients in the recovery room prior to the removal of the patient's breathing tube. The commenter further stated that the November 27, 2006 final rule (71 FR 68683) titled "Hospital Conditions of Participation" acknowledged CRNAs as ordering providers.

Response: This regulation does not change eligibility to order and certify for any provider type and only addresses enrollment for those professionals eligible to order and certify under existing law. Therefore, this suggestion is outside the scope of this final rule.

Comment: A few commenters questioned if enforcement of the enrolled physician requirement would be limited to payment prohibitions for ordered and referred items and services only, or if there would be survey and certification implications for a home health agency that is furnishing home health services based on a certification from a physician who is licensed but who does not have an approved enrollment record or a valid opt-out record in PECOS.

Response: Nothing in the IFC or this final rule changes our current survey and certification policies.

r. Summation and Final Decisions

After reviewing the public comments summarized in this section (section II.B.4. a. through q. of this final rule), we are finalizing the provisions regarding ordering and certifying of covered items and services for Medicare beneficiaries with several modifications. We want to start by clarifying two major modifications to this final rule from the IFC. First, we stated in the IFC that we would reject, not deny, claims from providers and suppliers that do not comply with these ordering and certifying requirements. After reviewing the comments, we have determined that we will deny such claims to provide the suppliers, providers, and beneficiaries with appeal rights. However, until further notice, we will not activate the automated edits that would cause a claim not to be paid for lack of an approved enrollment record in Medicare

or a valid opt-out status. We want to assure the beneficiary, provider, and supplier communities that we will provide advance notice before activating the edits by conducting appropriate outreach through our established channels including listservs, Medicare Learning Network (MLN) articles, and open door forums.

Second, we modified this final rule to permit residents, as defined in § 413.75, who are enrolled in an accredited graduate medical education program in a State that licenses or otherwise enables such individuals to practice or order these items or services to enroll in Medicare to order and certify. In situations where States do not license or otherwise permit such individuals to practice or order and certify services, the teaching physician's full legal name and NPI must be included on the claim as the person who ordered or certified the service. In this latter circumstance, the claims will not be paid unless the ordering and certifying physician, in this case, the teaching physician, is listed on the claim as the ordering or certifying physician. We made this change to assist teaching hospitals, as well as the providers and suppliers who render the items and services in complying with this rule.

Among the other changes to this section and in response to numerous comments received, we have changed the enrollment requirement language from one requiring enrollment in PECOS to one requiring enrollment in Medicare—including PECOS or other Medicare enrollment systems. We believe that this will reduce the number of claims that are denied or rejected and enable more currently enrolled physicians and practitioners to order or certify services.

We clarified our language in this provision to refer to the specific items and services the rule covers. After review of the public comments we received, we removed the language referring to "ordered or referred covered Part B items and services (excluding home health services described in § 424.507(b) and Part B drugs)." In this final rule, we specifically designate the covered items and services as follows: DMEPOS items, clinical laboratory, imaging, and home health services. Note that we have removed specialist services from the requirements of this rule.

We have also clarified our language with respect to the home health provision of this final rule. The IFC stated that physicians who order home health services must be listed on the claim for payment. However, to be technically correct, we have clarified our language in this final rule to state

that those who order/certify must be listed on the claim for payment. A commenter noted that these physicians may be one single physician or separate physicians. To that end, we have clarified our regulatory language to accommodate this public comment. Further, the statutory language at section 6405 of the Affordable Care Act specifically mentions application to the ordering *and* certifying physician. Therefore, we have clarified this language to be precise and more in conformity with the statutory language.

Finally, as more of a technical correction, we have removed all references to beneficiary-submitted home health claims. After considering comments received on this topic, we now agree that home health claims cannot be submitted by beneficiaries and thus, should not be included in this final rule.

C. Requirement for Physicians, Other Suppliers, and Providers to Maintain and Provide Access to Documentation on Referrals to Programs at High Risk of Waste and Abuse

1. Background

We believe it is imperative to establish accountability measures to ensure compliance with the ordering and referring provisions. To this end, the IFC implemented an Affordable Care Act provision by adding a new provision at § 424.516(f) that required providers and suppliers to maintain ordering and referring documentation, including the NPI, received from a physician or eligible non physician practitioner for 7 years from the date of service. The IFC also established in § 424.535(a)(10) that failure to comply with the documentation requirements specified in § 424.516(f) is a reason for revocation.

2. Provisions of the Affordable Care Act

Section 6406 of the Affordable Care Act amended section 1842(h) of the Act by adding a new paragraph which states, "The Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier under section 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary."

Section 6406(b)(3) of the Affordable Care Act amends section 1866(a)(1) of the Act to require that providers and suppliers maintain and, upon request, provide to the Secretary, access to written or electronic documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider as specified by the Secretary. Section 6406(b)(3) does not limit the authority of the Office of Inspector General to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

3. Requirements Established by the IFC

The IFC amended paragraph (f) of § 424.516 to require the following:

- A provider or supplier that furnishes covered ordered items of DMEPOS or home health, laboratory, imaging, or specialist services, to maintain written and electronic documentation (to include the NPI of the ordering or referring physician or eligible professional) relating to written orders and requests for payments for those items or services for 7 years from the date of service, and provide CMS or a Medicare contractor access to that documentation.
- A physician who ordered home health services and a physician or an eligible professional who ordered or referred DMEPOS, laboratory, imaging, and specialist services to maintain documentation relating to the written orders and requests for payments for those items or services for 7 years from the date of the order, certification, or referral and, upon request of CMS or a Medicare contractor, provide access to that documentation.

The IFC added paragraph (10) to § 424.535(a) to state that the Secretary may revoke Medicare enrollment and billing privileges for a period of not more than 1 year for each act of noncompliance for failure of a provider or supplier, including physicians and other eligible professionals, to comply with the document retention and access to documentation requirements at § 424.516(f).

4. Summary of and Responses to Public Comments on the Medicare Requirement for Physicians, Other Suppliers, and Providers to Maintain and Provide Access to Documentation on Referrals to Programs at High Risk of Waste and Abuse

a. Document Retention

Comment: A commenter asked if a home health agency would be

considered to have forged documentation if the documentation to be required could not be produced by the physician but could be found in the home health agency's documentation.

Response: This final rule places the responsibility for the maintenance of records on both the ordering and certifying physician and the provider and supplier. We require that a good faith effort is made to comply with this rule. However, we understand that from time to time situations arise that are outside of the control of these custodians. In such a case, we may conduct an analysis based on the specific facts and circumstances involved in a particular case.

Comment: A commenter noted that it will take some time for eligible professionals who will be enrolling in Medicare only to order and refer to fully understand their compliance obligations. In addition, dentists with practice management software and/or electronic records may be required to consult with their vendors and reconfigure their systems in order to comply with the documentation and disclosure requirements.

Response: Dentists and others who will be enrolling only to order should be fully aware of the documentation retention and disclosure requirements beforehand. We have already published considerable information about these requirements and have communicated directly and in numerous open door forums about these requirements. We will publish additional guidance, as appropriate, via a Medicare Learning Network product, messages in our provider/supplier listservs, and presentations at our provider/supplier open door forums. We will also continue to provide information directly to the ADA, DoD, DVA, PHS, and other affected employers of physicians and other eligible professionals who enroll in Medicare just to order and certify.

Comment: A commenter requested that CMS create exceptions to the penalty for non-compliance with the documentation retention and disclosure requirements. The commenter stated that there could be situations where documentation is destroyed or lost prior to the end of the 7-year required retention period, despite a provider's good faith efforts, due to circumstances beyond the provider's control, such as a systems malfunction or a natural disaster. The commenters stated that such providers or suppliers should not be penalized in the same manner as a provider or supplier who intentionally or carelessly disregards the documentation requirements. The commenter noted that the Act gives the

Secretary the authority to modify the penalties, as it states that “* * * the Secretary *may* revoke enrollment, for a period of not more than one year for each act.” (Italics added for emphasis.) The commenter believed that blanket penalties may be inequitable in practice and may create a potential disincentive to participate in Medicare.

Response: Medical documentation must be stored in a manner consistent with applicable security and privacy rules. However, we recognize that there could be circumstances in which an event could occur as indicated by the commenter. Therefore, as provided in § 424.535(a), a revocation action is discretionary and we would base a revocation decision on a complete analysis of the facts and circumstances prior to making a determination.

Comment: A commenter stated that a referral to home health care or for DMEPOS at a hospital or nursing home discharge would typically be retained in that hospital's or nursing home's records, not by the physician in his/her records.

Response: The physician or other eligible professional who signed the order or certification is responsible for maintaining and disclosing the documentation. We will provide further guidance on this after the publication of this final rule.

Comment: A commenter suggested that CMS only require document retention related to billable services for home health services by physicians (that is, the certification documents and, when care plan oversight reimbursement is sought, supporting documentation of time spent on such activities). The commenter stated that the documentation retained by physicians who are employed by providers or suppliers is governed by the requirements of the provider or supplier, not the physician. The commenter also stated that while revocation in Medicare of the physician may be appropriate for evidence of fraud or abuse, it would not be appropriate if a physician's employer lost or misfiled records. Several commenters stated that the added documentation requirements for DMEPOS and home health services are not clear and do not specify the specific kinds of documents that must be retained. Another commenter asked for specifics concerning the preferred format of retained information.

Response: This rule does not address the content or format of documentation that must be maintained and disclosed. However, for purposes of clarification, we suggest that a reasonable approach is for providers and suppliers to retain

documentation that supports the payment of the claim. This could include laboratory or other test results or findings and office visit notes in addition to copies of signed orders and certifications. We note that this documentation requirement applies to paper and electronic documents, as indicated in the statute and this final rule.

Comment: A commenter questioned whether the documentation requirements require that a supplier use electronic medical records. The commenter states that if a supplier is going to be required to use electronic medical records, the financial burden would put many small suppliers out of business.

Response: The requirements at § 424.516 does not require providers and suppliers to use electronic medical records.

Comment: A commenter questioned if the failure of a physician to retain a copy of the CMS-485 could lead to denial of claims and recoupment of prior payments from home health agencies.

Response: As stated earlier, this rule does not modify or address the content requirements for documents to be retained. Therefore, this comment is outside of the scope of this final rule.

Comment: Some commenters requested that CMS to specifically identify the entities or individuals to whom such documentation must be disclosed (for example, CMS or its contractors, an Administrative Law Judge, a DMEPOS supplier, and a beneficiary).

Response: Disclosure is required to be made, upon request, to CMS or CMS contractors. Disclosure may also be requested by DHHS OIG for fulfillment of the Inspector General's responsibilities and under its independent authority. However, this list is not exhaustive and other agencies such as the Department of Justice (DOJ) and the Internal Revenue Service (IRS) have separate authority to request documentation.

Comment: A commenter stated that interns and residents may be responsible for creating, and the dental school clinic may be responsible for retaining, the records required to comply with section § 424.516(f)(2); and that other dentists, such as locum tenens dentists and those who are employed by a government agency or a group practice, may not be capable of maintaining independent documentation of orders and referrals and may not be able to grant CMS or a Medicare contractor access to those records. This commenter asked CMS to

clarify how the requirements in this section would apply to dentists. This commenter also urged that a dentist who is unable to comply with a disclosure request because another person or entity has control over the documentation not be subject to revocation of enrollment and billing privileges in Medicare under § 424.535(a)(10).

Response: The requirements of § 424.516(f)(2) apply to interns, residents, and dentists in the same way they apply to enrolled physicians and to other eligible professionals. We will provide further guidance on this during the implementation of the provisions contained in this final rule.

Comment: Several commenters stated that the document retention requirements vary considerably depending on different parts of the Medicare program. Physicians do not know how long they need to retain certain records. We should provide education to physicians on document retention requirements for various parts of the Medicare program.

Response: This final rule does not address documentation requirements (for example, those found in § 420.300 through § 420.304) for other parts of the Medicare program other than documentation retention and provision requirements related to particular items and services that are ordered and certified. Some aspects of this comment are outside the scope of this final rule. We are requiring that documentation pertaining to ordered and certified services and supplies be retained for 7 years, as specified in § 424.516(f). We will continue to provide educational material to the public as we implement the specific provisions in this final rule.

Comment: Several commenters stated that the documentation requirements should apply only to the imaging facility (the technical component provider) and not the ordering or referring provider or the interpreting physician. To require the ordering or referring provider or the interpreting physician to maintain documentation is unnecessary and is a duplication of effort and expense, and many such providers are currently ill-equipped to do this. Ordering physicians do not differentiate between the technical and professional components of their order; they assume both will occur.

Response: We are not placing documentation requirements on physicians who interpret imaging tests. Section 1866(a)(1)(W) of the Act authorizes the Secretary to extend these requirements to other items and services. Section 424.516(f)(1) and at § 424.535(a)(10) apply to home health

agencies, DMEPOS suppliers, clinical laboratories, imaging centers, and those physicians and other eligible professionals who ordered or certified home health, DMEPOS, clinical laboratory, and imaging services.

Comment: Many commenters stated that § 424.516 should not require maintenance of documentation related to requests by a physician that the patient see another physician. Section 424.516 should apply only to items and services for which Medicare requires a written order or referral (such as DMEPOS, home health, laboratory, and diagnostic tests).

Response: As stated earlier in this preamble, we have removed requirements for specialist services in § 424.507 and § 424.516 from this final rule.

Comment: Several commenters recommended that § 424.535 be revised to reflect less severe penalties for failure to retain and/or disclose documentation of orders and referrals. They suggested that allowing the recovery of applicable Medicare payments and the establishment of and compliance with a corrective action plan be the required penalties for noncompliance.

Response: This regulation implements section 6406 of the Affordable Care Act which amended section 1843(h) of the Act. Section 1842(h)(9) of the Act states,

The Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier under section 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary.

We believe that the penalties to be imposed are appropriate and in accordance with the statute.

Comment: A commenter recommended that the stated documentation requirements at § 424.516(f) be revised to limit physician documentation requirements to a copy of the home health Plan of Care and the certification/recertification forms, and not to require retention of interim orders except when they are for added billable services and not to require a physician's NPI on the certification/recertification form or interim orders for added billable services until CMS issues detailed guidance for the content of the Plan of Care, including specific physician's NPI requirements.

Response: As noted in earlier responses, this final rule does not

provide an exhaustive list of the documentation to be retained and produced if requested. However, any documentation that supports the payment of the claim should be retained and must be made available upon request. The NPI of the ordering or certifying provider must be included in the retained documentation.

b. Technical, Administrative, and Procedural Modifications and Corrections

Comment: Several commenters noted that the requirements added at § 424.507 apply to Part B items and services (excluding Part B drugs) and Part A and Part B home health services, whereas the documentation requirements added at § 424.516 apply to a narrower set of services (that is, § 424.516 specifically states DMEPOS, home health, laboratory, imaging, and specialist services). The commenters stated that CMS should apply the document retention requirements and the ordering or referring provider enrollment requirements to the same types of orders and referrals.

Response: We have revised the regulatory text for consistency. The ordering and certifying requirements and the documentation requirements apply to the same items and services, specifically: DMEPOS, imaging and clinical laboratory services, and home health services.

c. Public Comments Outside the Scope of the Requirement To Maintain and Provide Access to Documentation of Referrals

Comment: A commenter stated that the documentation requirement could have a significant impact on patients who present for services or supplies with an order that is not signed. The patient may be delayed in receiving medically necessary care while the provider or supplier who would furnish the item or service requests a signed order. Obtaining the signature places a burden on the provider or supplier who would furnish the service.

Response: We believe this comment is outside of the scope of this final rule because we are not modifying requirements for orders to be signed.

Comment: A commenter stated that the need to produce I-9 forms for foreign born suppliers is administratively burdensome on large provider groups.

Response: Production of an I-9 form for foreign born suppliers is not a requirement of this final rule and therefore outside of the scope of issues to be addressed.

d. Summation and Final Decisions

After review of the all of public comments presented this section (section II.C.4. a. through c. of this final rule), we are finalizing the document retention requirements with several modifications. We are revising the provisions to follow the ordering and certifying provisions' covered items and services to include DMEPOS, laboratory, and imaging services, and home health services. We have also clarified that document maintenance and affording access to documentation, with regard to the home health provision, applies to orders and certifications. This provision has been clarified for the same reasons we clarified § 424.507, as described herein.

We have clarified that documents must be retained from the date of service, rather than the date of the order or certification- as specified in the IFC. Specialist services are no longer included in either the ordering and referring provision of § 424.507 or the document retention provision in § 424.516.

Section 424.535 remains unchanged in the fact that a provider or supplier that does not meet the requirements of § 424.516 is subject to revocation for not more than 1 year for each act of noncompliance. Finally, as a technical correction, we removed a provision in § 424.535 that references section 1866(j) of the Act.

III. Provisions of the Final Rule

In this section of the final rule, we discuss the changes made from the IFC. We are finalizing the provisions of the IFC with the modifications based on our response to comments and other statutory and technical changes stated in this section of the final rule.

In section II.A. of this final rule, we discuss the inclusion of the NPI on all Medicare enrollment applications, pursuant to Medicaid provider agreements, and on Medicare and Medicaid claims. We note that the main objectives of that section remain constant from the IFC to this final rule in that providers and suppliers must provide their NPIs as a part of their enrollment record. Furthermore, this NPI must be reported on any claims for payment, along with the NPI of any other provider or supplier listed on the claim form. We made a few modifications to the NPI provisions included in the IFC. In § 424.506, we made the following changes:

- Revised paragraph (b)(1) to include the text of paragraph (b)(2).
- Removed the existing paragraph (b)(2) and redesignated paragraph (b)(3) and paragraph (b)(2).

- Paragraph (c)(1) was revised to insert the word "must" between the words "Medicare" and "include" because the word was inadvertently omitted in this requirement in the IFC.

In section II.B. of this final rule, we discuss our provisions regarding ordering and certifying covered items and services for Medicare beneficiaries. In that section of this final rule, set forth are specific provider and supplier mandates for enrolling in Medicare to order and certify certain, specified items or services including DMEPOS, laboratory and imaging services, and home health services. We stress that this rule finalizes conditions of payment for ordered items and services, and it does not address broader payment policy questions. It neither changes eligibility requirements that permit certain provider types to order or certify, nor does it detail which items or services they are permitted to order or certify. This rule, in its applicable sections, only addresses the enrollment requirements for those eligible professionals who are permitted to order and certify under existing rules. We are making the following modifications regarding ordering and certifying covered items and services for Medicare beneficiaries:

- In § 424.507, we made the following changes:

++ Revised the introductory text for paragraph (a) to clarify the items and services to which this paragraph applies (covered Part B DMEPOS items and clinical laboratory and imaging services). We also deleted the reference to specialist services.

++ Revised paragraph (a)(1) by inserting the word "claim" between the words "supplier's" and "must."

++ Revised paragraph (a)(1)(iii) to state that the physician or other eligible professional, when permitted, must be enrolled in Medicare in an approved status or have validly opted- out of the Medicare program.

++ Revised paragraph (a)(1)(iv) to require that claims identify the teaching physician as the ordering or certifying provider when an unlicensed resident or a non-enrolled licensed resident orders or certifications. We are also providing the option of enrollment if residents possess a provisional license or are otherwise permitted by their State to practice or order and certify.

++ Revised paragraph (a)(2)(iii) to be consistent with paragraph (a)(1)(iii).

++ Revised paragraph (a)(2)(iv) to be consistent with paragraph (a)(1)(iv) by requiring that claims identify the teaching physician as the ordering or certifying provider when an unlicensed resident or a non-enrolled licensed

resident orders or certifications. We are also providing the option of enrollment if residents possess a provisional license or are otherwise permitted by their State to practice or order and certify.

++ Revised paragraph (b)(3) (formerly paragraph (b)(1)(iii)) to be consistent with paragraph (a)(1)(iii) by requiring that home health claims identify the teaching physician as the ordering/ certifying provider when an unlicensed resident or a non-enrolled licensed resident certifies. We are also providing the option of enrollment if residents possess a provisional license or are otherwise permitted by their State to order/certify or practice.

++ Removed the requirements for home health claims submitted by Medicare beneficiaries in paragraph (b)(2). This change resulted in the rewording of the title of paragraph (b) to read: "Conditions for payment of claims from home health providers for covered home health services" and the renumbering of the requirements in paragraph (b).

++ Revised paragraph (b) by removing the word "ordered" from the provision. This change will result in the wording as follows: "To receive payment for covered Part A or Part B home health services, a provider's home health services claim must meet all of the following requirements:"

++ Revised paragraph (b)(1) and (b)(2) (formerly paragraph (b)(1)) to include certifications, not simply orders for home health.

++ Revised paragraph (c) to state that we will deny a claim from a provider or supplier for covered services described in § 424.507(a) and § 424.507(b) if the claim does not meet the requirements of § 424.507(a)(1) and § 424.507(b), respectively. We also changed the reference from § 424.507(b)(1) to § 424.507(b).

++ Revised paragraph (d) to remove the references to sections that relate to home health services and home health claims, as Medicare beneficiaries do not submit claims for home health services.

In section II.C. of this final rule, we discuss the IFC provisions regarding document retention requirements. We are finalizing these requirements with the following modifications:

- In § 424.516, we made the following changes:

++ Removed the words "specialist services" in paragraph (f)(1) and we more specifically described the items and services to which the final rule applies.

++ Revised paragraph (f)(2) to more specifically describe the items and services to which this final rule applies.

++ Revised paragraphs (f)(1) and (f)(2) to more explicitly describe the home health events to which this final rule applies by specifically referring to orders and certifications.

- In § 424.535(a)(10)(i), we removed the reference to section 1866(j) of the Act.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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.

A. ICRs Regarding National Provider Identifier (NPI) on All Medicare Enrollment Applications and Claims (§ 424.506)

Section 424.506(b)(1) states that providers and suppliers who are eligible for NPIs be required to report their NPIs on their enrollment applications for Medicare. Similarly, § 424.506 (b)(2) states that if providers or suppliers enrolled in Medicare prior to obtaining NPIs and their NPIs are not in their enrollment records, they must submit enrollment applications containing their NPIs.

The burden associated with the requirements in § 424.506(b) is the time and effort necessary for a provider or a supplier to apply for an NPI and the time and effort necessary to report the NPIs on their enrollment applications for Medicare.

Sections § 424.510 and § 424.515 state that providers and suppliers must submit enrollment information on the applicable enrollment application and update, resubmit, and recertify the accuracy of their enrollment information every 5 years. In addition, § 424.516 lists reporting requirements for providers and suppliers. To submit enrollment information for an initial application (even if enrolling just to

order and certify), a change of information, or to respond to a revalidation request, a provider or supplier must complete and submit the applicable CMS-855 form or complete and submit the form over the Internet using Internet-based PECOS. Although we are unable to quantify the number, we do not believe that a significant number of physicians and eligible professionals will enroll in Medicare just to order and certify. The burden associated with the enrollment requirements found in § 424.510, § 424.515, and § 424.516 is the time and effort necessary to complete and submit applicable Medicare form. While this burden is subject to the PRA, it is currently approved under existing OMB control numbers (OCN). Specifically, the burden associated with obtaining an NPI is currently approved under OCN 0938-0931. The burden associated with submitting initial Medicare enrollment applications and updating Medicare enrollment information to include NPI is approved under OCN 0938-0685 (Applications CMS-855 A, B, I, and R) 0938-1056 (Application CMS-855 S).

Section 424.506(b)(1) states that providers and suppliers who are enrolled in Medicare must report their NPIs and the NPIs of any other providers or suppliers who are required to be identified in their claims on all paper and electronic claims that they send to Medicare. The burden associated with this requirement is the time and effort necessary to complete and submit a claim form. The burden associated with this collection is accounted for under OCN 0938-0999. We are currently seeking reinstatement of the control number.

B. ICRs Regarding Ordering and Referring Covered Items and Services for Medicare Beneficiaries (§ 424.507)

Section 424.507 states that to receive payment for covered Part A or Part B home health services, the claim must contain the legal name and the NPI of the ordering physician; and to receive payment for covered items of DMEPOS, and certain other covered Part B items or services (excluding Part B drugs), the claim must contain the legal name and the NPI of the ordering or certifying physician or eligible professional. The burden associated with these requirements is the time and effort necessary to submit a claim with the required information. The burden associated with this collection is accounted for under OCN 0938-0999. We are currently seeking reinstatement of the control number.

C. ICRs Regarding Additional Provider and Supplier Requirements for Enrolling and Maintaining Active Enrollment Status in the Medicare Program (§ 424.516)

Section 424.516(f)(1) discusses the documentation requirements for providers and suppliers. A provider or supplier is required for 7 years from the date of service to maintain and upon request of CMS or a Medicare contractor, provide access to documentation, including the NPI of the physician or the eligible professional who ordered or certified the item or service, relating to written orders or requests for payments for items of DMEPOS, home health, laboratory, and imaging services. Similarly, § 424.516(f) discusses the documentation requirements for providers and suppliers. At § 424.516(f)(1), providers and suppliers are required for 7 years from the date of service to maintain and, upon request of CMS or a Medicare contractor, provide access to documentation, including the NPI of the physician or the eligible professional who ordered or certified the item or service, relating to written orders or requests for payments for items of DMEPOS, home health, laboratory, and imaging services. At § 424.516(f)(2), physicians and eligible professionals are required for 7 years from the date of service to maintain and, upon request of CMS or a Medicare contractor, provide access to written and electronic documentation relating to written orders or certifications for items of DMEPOS, home health, laboratory, and imaging services.

The burden associated with the requirements in § 424.516(f) is the time and effort necessary to both maintain documentation on file and to furnish the information upon request to CMS or a Medicare contractor. While the requirement is subject to the PRA, we believe the associated burden is exempt. As discussed in the November 19, 2008 final rule (73 FR 69726), we believe the burden associated with maintaining documentation and furnishing it upon request is a usual and customary business practice and thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

D. ICRs Regarding the Reporting of National Provider Identifier by Medicaid Providers (§ 431.107(b)(5))

Section 431.107(b)(5) states that a Medicaid provider has to furnish its NPI (if eligible for an NPI) to its State agency and include its NPI on all claims submitted under the Medicaid program. The burden associated with the Medicaid requirements in

§ 431.107(b)(5) is the time and effort necessary for a provider to report the NPIs to the State agency and on claims submitted to the Medicaid program.

1. Enrollment Applications

We have considered the burden associated with enrollment applications for Medicaid by estimating the number of providers. Specifically—

- There will be 56,250 Medicaid and CHIP providers in a given 12-month period that seek to enroll in Medicaid; and

- According to State Program Integrity Assessment data for FFYs 2007 and 2008, there has been an average of 1,855,070 existing Medicaid and CHIP providers nationally over the 2-year period of FFYs 2007 and 2008. Of these 1,855,070 providers, approximately one-fifth of them, or 371,014 ($1,855,070 \times .20$), would be required to revalidate their enrollment each year under § 431.107(b).

For purposes of this paperwork burden assessment only, we assumed that 427,264 providers ($56,250 + 371,014$) will either initially enroll in or be required to revalidate their enrollment in Medicaid and, as part of this, be required to report their NPI.

We recognize that not all of these providers will have NPIs to report; a very small percentage of them may be exempt from having to obtain an NPI. We further understand that: (1) Some States may choose to allow (or even require) providers to submit their NPIs via mechanisms that are potentially less burdensome than submitting an initial enrollment or revalidation application; and (2) the previous figures include CHIP providers, who are not subject to the requirements of § 431.107(b). However, we chose to utilize the 427,264 figure and the application reporting mechanism for this paperwork burden assessment, so as not to underestimate the potential burden of this particular requirement. We estimated that it will take an average of

less than 1 minute (or 0.01666 hours) for a medical technician to report a Medicaid provider's NPI to the State agency on an enrollment or reenrollment application. However, we assumed 1 minute for purposes of this burden. This results in an annual hour burden of 7,118 hours (or $427,264 \times 0.01666$). At a per hour cost of \$14.51, according to the Bureau of Labor Statistics (BLS) for May 2011 for the mean hourly wage of a medical assistant, we projected a total annual cost of \$103,282.

2. Claims

In FY 2008, approximately 2.5 billion Medicaid claims were submitted. This number has remained relatively constant since then.

As of May 23, 2008, and consistent with 45 CFR 162.410, the NPI has been required for all HIPAA-standard transactions. This means that Medicaid providers have been required since that date to disclose their NPI on all HIPAA-standard transactions, which we estimate to represent about 95 percent of all Medicaid claim submissions. We arrived at this percentage because we polled 10 States and using their individual percentage of electronic claims submission compiled an average of 95 percent. We then applied that percentage to the nation since 10 States we polled represent a sample of small and large States as well as States with a low and high Medicaid population and therefore we believe can be considered an adequate sample.

We will not be furnishing an estimated burden for the requirement that a provider furnish its NPI on claims because this requirement already applies to the vast majority of Medicaid claims under § 431.107(b)(5), and 45 CFR 162.410. The burden we estimate here will be for those claims—in general, paper claims—that are not HIPAA-standard transactions but that now must contain the NPI per § 431.107(b)(5). It is true that some

States have been requiring the submission of the NPI on all Medicaid claims, even those that are not subject to § 431.107(b)(5). However, no burden has been prepared for this. We do so in this final rule.

We projected that 5 percent of the 2.5 billion claims previously referenced—or 125 million—will not qualify as HIPAA-standard transactions. These claims will need to contain the provider's NPI. We estimate that it will take the provider/medical assistant less than 1 minute to add the NPI to the claim but for purposes of the burden we estimated 1 minute—or 0.01666 hours—to furnish its NPI on the claim. This results in an annual burden of 2,082,500 hours. At a per hour cost of \$14.51, we project the annual cost of this requirement to add the NPI to paper or non-HIPAA standard transactions to be \$30,317,075. We wish to point out that as a result of this final rule, all claims will be required to have an NPI so as States implement these requirements, the burden will continue to decrease. Of note, while we received no comments on the burden for appending the NPI to the Medicaid provider agreement and/or the Medicaid claims for payment, we have updated these estimates to account for a medical assistant rather than a medical technician, since we believe a medical assistant is more likely to provide administrative support to the provider and to account for the May 2011 BLS mean hourly wage of a medical assistant rather than the 2008 mean hourly wage of the medical technician.

Table 1 indicates the paperwork burden associated with the requirements of this final rule. The only two requirements listed are those involving the Medicaid NPI provisions described in § 431.107(b)(5). The remaining requirements, as explained above, are either exempt from the PRA requirement or the burden for them has been addressed in other PRA packages/assessments.

TABLE 1—ESTIMATED AVERAGE ANNUAL REPORTING/RECORDKEEPING BURDEN

Regulation section	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
431.107(b)(5)—Enrollment	0938—New ..	427,264	427,264	0.01666	7,118	14.51	103,282	0	103,282
431.107(b)(5)—Claims	0938—New ..	2,500,000,000	125,000,000	0.01666	2,082,500	14.51	30,317,075	0	30,317,075
Total		2,500,427,264	125,427,264		2,089,618				30,320,357

If you comment on these information collection and recordkeeping requirements, please submit your

comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS—6010–F.

Fax: (202) 395–6974; or

Email:

OIRA_submission@omb.eop.gov.

In response to our solicitation of comments on these issues, we received the following comments:

Comment: A commenter believed that CMS should re-estimate the actual burden of completing the CMS-855I enrollment applications with respect to the burden required by this final rule, including contractor processing time and the interruption of Medicare reimbursement for the physician.

Response: With respect to the completion of CMS-855 form pursuant to the final rule, we believe that the overall burden will, in general, be increased only by the number of individuals who are enrolling just to order and certify via the new CMS-855O form, as most other physicians and eligible professionals who order and certify have already enrolled in Medicare via the CMS-855I. In other words, the new burden relates to the CMS-855O, not the CMS-855I. As explained later in this section, the burden associated with completing the new CMS-855O form was addressed in the Paperwork Reduction Act (PRA) package for that form.

Comment: A commenter stated that the costs of preparing and filing correspondence and records (paper, or scanned from paper and put into an electronic record) would be astronomical, with no evidence of benefit in fraud prevention or detection.

Response: This final rule does not address the format, context, or mode of documentation. However, for purposes of clarification, we do not require that paper documentation be converted into electronic format in order to meet the documentation and disclosure requirements of this final rule. Moreover, we believe that such document retention is a normal and customary business practice. As such, we do not foresee additional costs associate with a practice that is already in existence for many providers.

Comment: Several commenters questioned what is meant by the phrase “providing access to that documentation.” If this means that physician specialty practices will have to allow CMS or its contractor access to their patient records, it would be burdensome and disruptive to the practices and could create potential patient privacy problems. This would be even more difficult for electronically maintained records.

Response: CMS, its contractors, and/or the DHHS OIG may request access to required documentation. It is the responsibility of the provider and supplier, and of the physician or other

eligible professional, or their provider/supplier employers, where appropriate and as discussed earlier, to determine the method of storage of the required documentation, the location of the stored required documentation, and the means by which it will disclose the required documentation to CMS, its contractors, and/or the DHHS OIG in order to comply with this final rule. Medical practices and other employers that are responsible for the documentation and disclosure requirements must ensure that they can meet these requirements in order to remain active in the Medicare program.

Comment: Several commenters stated that the IFC does not include an adequate analysis of the impact of the expanded documentation requirement for physicians. Repeated audits over a 7-year period of time is not part of a regular administrative work flow and will cause considerable financial burden, absorb staff time, and require investment in the maintenance of documentation. Small medical practices do not have the necessary resources to do this.

Response: We do not foresee providers, suppliers, physicians, etc., being subjected to “repeated” audits. To the contrary, such audits will, in general: (1) Be performed only as an “as needed” basis, and (2) merely involve requests for limited numbers of documents. Moreover, we believe that such infrequent audits are, like documentation retention, normal business practices. It is not altogether uncommon, for example, for a private health insurance plan—as part of an investigation—to request certain documentation from a supplier in order to support the need for a particular service that was provided.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary to finalize provisions of the May 5, 2010 IFC. As discussed earlier, the IFC implemented several provisions of the Affordable Care Act:

- Section 6402(a), which requires all Medicare and Medicaid providers of medical or other items or services and suppliers that qualify for a National Provider Identifier (NPI) to include the NPI on all Medicaid provider agreements, Medicare enrollment records, and Medicare and Medicaid claims for payment.
- Section 6405, which requires physicians or eligible professionals who order and/or certify Medicare services to be enrolled in Medicare.

- Section 6406, which requires physicians and suppliers to maintain and provide access to documentation relating to written orders or requests for payment for DMEPOS, HHA, and other services as specified by the Secretary.

We also believe that this final rule is needed to help ensure that (1) accurate claims are submitted; (2) the Medicare items and services being ordered and/or certified are valid and necessary; and (3) appropriate records of orders and certifications for Medicare items and services are maintained.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulations 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 directs 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any single year). As discussed in more detail later in this section, we believe that the savings resulting from this final rule will exceed \$100 million in each of the next 10 fiscal years, beginning in fiscal year (FY) 2013. Therefore, this is an economically significant rule based upon section 3(f)(1) of Executive Order 12866.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief for small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.0 million to \$34.5 million in any one year).

Individuals and States are not included in the definition of a small entity. As we stated in the IFC, we do not believe that this rule will have a significant economic impact on a substantial number of small entities. Nonetheless, we recognize that the potential effects of this final rule could impact some providers of covered imaging, clinical laboratory, DMEPOS, and home health items and services. We have therefore, elected to prepare a voluntary RFA analysis. As many of the requirements of the RFA are contained in our RIA, this RIA section also constitutes the RFA. Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act. The Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

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 2011, that threshold is approximately \$136 million. This final rule does not mandate expenditures by either the governments mentioned or the private sector; therefore, no analysis is required.

Executive Order (EO) 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. Since this regulation does not impose significant costs on State or local governments, the requirements of E.O. 13132 are not applicable.

C. Anticipated Effects

As previously stated, we project, based on internal CMS data, that the total savings to the Federal government resulting from this final rule will exceed \$100 million in each of the next 10 fiscal years. The total savings at the end of this 10-year period is estimated to be \$1.59 billion. This figure accounts for our estimates that: (1) Approximately 5 percent of physicians will not be

enrolled; (2) such physicians have only 50 percent as many Medicare enrollees as other physicians; and (3) 10 percent of patients of those physicians will not seek out enrolled physicians. The product of these is inflated by 25 percent to account for other providers who could potentially order services. The net result is roughly a 0.3 percent—or \$1.59 billion—reduction in DMEPOS, imaging and clinical laboratory services, and Part A and Part B home health costs over the next 10 years attributable to patients who will choose not to seek out an enrolled physician to obtain such services. In addition, some claims without proper documentation will be denied, including some fraudulent claims, but we do not have a basis for quantifying the value of such claims.

Table 2 outlines the year-by-year projected savings to the Federal government over the next decade.

TABLE 2—PROJECTED SAVINGS

Fiscal year	Savings * (in \$millions)
2013	110
2014	120
2015	130
2016	140
2017	150
2018	160
2019	180
2020	190
2021	200
2022	210
Total	1,590

* In actual dollars for the years presented.

We believe that the rule's other effects will be minimal. With respect to § 424.506, practically all providers and suppliers that wish to enroll in Medicare and Medicaid programs have already obtained NPIs and are currently meeting requirements regarding the need to report their NPIs on, as applicable, enrollment applications and claims. Regarding § 424.516(f), we believe that most providers and suppliers already retain such documentation as a usual and customary business practice.

D. Alternatives Considered

Since this final rule is a codification of statutory provisions found in the Affordable Care Act, we did not consider alternatives to the overall processes described in the IFC. We did consider the possibility of including additional items and services on the list of those affected by this final rule. However, while we have the authority under section 6405(c) of the Affordable Care Act to expand the requirements of section 6405(a) and (b) of the Affordable

Care Act to all other categories of items or services under Title XVIII of the Act, we chose to expand these requirements only to clinical laboratory and imaging services, rather than to many other types of services. (Specialist services, moreover, are no longer covered by the requirements of this final rule.) We believe that the application of these requirements to limited categories of items and services will ease the overall burden on the provider and supplier communities. Moreover, in response to comments on the IFC, we considered and adopted the following alternatives that we believe will further the impact of these provisions.

First, we state in § 424.507 that in order for a claim to be paid, the ordering physician/practitioner must be enrolled in Medicare in an approved status or must have validly opted-out of the Medicare program. The IFC required that the ordering physician/practitioner have an approved enrollment record in PECOS. However, we have changed the enrollment requirement language from one requiring enrollment in PECOS to one requiring enrollment in Medicare—including PECOS or other Medicare enrollment systems. We believe that this will reduce the number of claims that are denied or rejected and enable more currently enrolled physicians and practitioners to order or certify for services.

Second, we will provide ample advanced notice of our intention to activate the automated edits that would cause a claim to not be paid for the lack of a valid: (1) Enrollment record to order and certify; or (2) a valid opt-out record in Medicare.

For Medicaid, again, we codified the statutory provisions found in the Affordable Care Act. However, we considered alternatives to the statute, since the provision requires all providers of medical or other items or services and supplies to include their NPI on all applications. Medicaid, until recently, had no Federally required process for provider enrollment outside of the requirement to enter into a provider agreement with the State. Further, Medicaid has no Federal process for applications to enroll in the Medicaid program. Thus, in order to comply with the statutory requirement outlined in 6402 of the Affordable Care Act to append the NPI to the application for enrollment, Medicaid considered codifying additional regulatory requirements outlining a Federal process for the application to enroll in Medicaid. Because of the Administration's goal to provide for greater administration simplification, we determined that Medicaid would not

prepare additional regulatory requirements but would provide that the NPI must be appended to the provider agreement. Since entering into a provider agreement with the State is currently a requirement in the Medicaid program, we believe this option provides States and providers with an alternative that is less burdensome.

Again, the main purpose of this final rule is to implement the previously referenced provisions of the Affordable Care Act. However, we also believe that these requirements will help to ensure that Medicare and Medicaid payments are correctly and properly made.

E. Accounting Statement

As required by OMB Circular A-4 (available at link http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf), we have prepared an accounting statement. In calculating the annualized savings in the accounting statement, we applied the 7 and 3 percent discount rates to the full 10-year period assessed.

TABLE 3—ACCOUNTING STATEMENT
[In \$millions]

Category	Primary estimate	Year dollars	Discount rate (percent)	Period covered
Transfers from Providers to the Federal government	\$136.8 139.1	2012 2012	7 3	FYs 2013–2022. FYs 2013–2022.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 431

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

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services is confirming as final the interim final rule amending 42 CFR parts 424 and 431 that published on May 5, 2010 (75 FR 24437) with the following changes:

PART 424—CONDITIONS FOR MEDICARE PAYMENT

- 1. The authority citation for part 424 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

- 2. Section 424.506 is amended by revising paragraphs (b) and (c)(1) to read as follows:

§ 424.506 National Provider Identifier (NPI) on all enrollment applications and claims.

* * * * *

(b) *Enrollment requirements.* (1) A provider or a supplier that is eligible for an NPI must do the following:

(i) Report its NPI on its Medicare enrollment application.

(ii) If the provider or supplier was in the Medicare program before obtaining an NPI and the provider's or the

supplier's NPI is not in the provider's or supplier's Medicare enrollment record, the provider or supplier must update its Medicare enrollment record by submitting its NPI using either of the following:

(A) The applicable paper CMS-855 form.

(B) Internet-based PECOS.

(2) A physician or eligible professional who has validly opted-out of the Medicare program is not required to submit a Medicare enrollment application for any reason, including to order or certify.

(c) * * *

(1) A provider or supplier that is enrolled in Medicare and submits a paper or an electronic claim must include its NPI and the NPI(s) of any other provider(s) or supplier(s) identified on the claim.

* * * * *

- 3. Section 424.507 is revised to read as follows:

§ 424.507 Ordering covered items and services for Medicare beneficiaries.

(a) *Conditions for payment of claims for ordered covered imaging and clinical laboratory services and items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).*

(1) *Ordered covered imaging, clinical laboratory services, and DMEPOS item claims.* To receive payment for ordered imaging, clinical laboratory services, and DMEPOS items (excluding home health services described in § 424.507(b), and Part B drugs), a provider or supplier must meet all of the following requirements:

(i) The ordered covered imaging, clinical laboratory services, and DMEPOS items (excluding home health services described in paragraph (b) of this section, and Part B drugs) must have been ordered by a physician or,

when permitted, an eligible professional (as defined in § 424.506(a) of this part).

(ii) The claim from the provider or supplier must contain the legal name and the National Provider Identifier (NPI) of the physician or the eligible professional (as defined in § 424.506(a) of this part) who ordered the item or service.

(iii) The physician or, when permitted, other eligible professional, as defined in § 424.506(a), who ordered the item or service must—

(A) Be identified by his or her legal name;

(B) Be identified by his or her NPI; and

(C)(1) Be enrolled in Medicare in an approved status; or

(2) Have validly opted-out of the Medicare program.

(iv) If the item or service is ordered by—

(A) An unlicensed resident (as defined in § 413.75), or by a non-enrolled licensed resident (as defined in § 413.75), the claim must identify a teaching physician, who must be enrolled in Medicare in an approved status, as follows:

(1) As the ordering supplier.

(2) By his or her legal name.

(3) By his/her NPI.

(B) A licensed resident (as defined in § 413.75), he or she must have a provisional license or be otherwise permitted by State law, where the resident is enrolled in an approved graduate medical education program, to practice or order such items and services, the claim must identify by legal name and NPI the—

(1) Resident, who is enrolled in Medicare in an approved status to order; or

(2) Teaching physician, who is enrolled in Medicare in an approved status.

(2) *Part B beneficiary claims.* To receive payment for ordered covered items and services listed at § 424.507(a), a beneficiary's claim must meet all of the following requirements:

(i) The physician or, when permitted, other eligible professional (as defined § 424.506(a)) who ordered the item or service must—

(A) Be identified by his or her legal name; and

(B)(1) Be enrolled in Medicare in an approved status; or

(2) Have validly opted out of the Medicare program.

(ii) If the item or service is ordered by—

(A) An unlicensed resident (as defined in § 413.75) or a non-enrolled licensed resident, (as defined in § 413.75) the claim must identify a teaching physician, who must be enrolled in Medicare in an approved status as follows:

(1) As the ordering supplier.

(2) By his or her legal name.

(B) A licensed resident (as defined in § 413.75), he or she must have a provisional license or are otherwise permitted by State law, where the resident is enrolled in an approved graduate medical education program, to practice or to order such items and services, the claim must identify by legal name the—

(1) Resident, who is enrolled in Medicare in an approved status to order; or

(2) Teaching physician, who is enrolled in Medicare in an approved status.

(b) *Conditions for payment of claims for covered home health services.* To receive payment for covered Part A or Part B home health services, a provider's home health services claim must meet all of the following requirements:

(1) The ordering/certifying physician must meet all of the following requirements:

(i) Be identified by his or her legal name.

(ii) Be identified by his or her NPI.

(iii)(A) Be enrolled in Medicare in an approved status; or

(B) Have validly opted-out of the Medicare program.

(2) If the services were ordered/certified by—

(i) An unlicensed resident, as defined in § 413.75, or by a non-enrolled licensed resident, as defined in § 413.75,

the claim must identify a teaching physician who must be enrolled in Medicare in an approved status—

(A) As the ordering/certifying supplier;

(B) By his or her legal name; and

(C) By his or her NPI.

(ii) A licensed resident (as defined in § 413.75), he or she must have a provisional license or are otherwise permitted by State law, where the resident is enrolled in an approved graduate medical education program, to practice or to order/certify such items and services, the claim must identify by legal name and NPI the—

(A) Resident, who is enrolled in Medicare in an approved status to order; or

(B) Teaching physician, who is enrolled in Medicare in an approved status.

(c) *Denial of provider- or supplier-submitted claims.* Notwithstanding § 424.506(c)(3), a Medicare contractor denies a claim from a provider or a supplier for covered items and services described in paragraph (a) or (b) of this section if the claim does not meet the requirements of paragraphs (a)(1) and (b) of this section, respectively.

(d) *Denial of beneficiary-submitted claims.* A Medicare contractor denies a claim from a Medicare beneficiary for covered items or services described in paragraphs (a) and (b) of this section if the claim does not meet the requirements of paragraph (a)(2) of this section.

■ 4. Section 424.516 is amended by revising paragraphs (f)(1) and (2) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(f) * * *

(1)(i) A provider or a supplier that furnishes covered ordered items of DMEPOS, clinical laboratory, imaging services, or covered ordered/certified home health services is required to—

(A) Maintain documentation (as described in paragraph (f)(1)(ii) of this section) for 7 years from the date of service; and

(B) Upon the request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(1)(ii) of this section).

(ii) The documentation includes written and electronic documents

(including the NPI of the physician who ordered/certified the home health services and the NPI of the physician or, when permitted, other eligible professional who ordered items of DMEPOS or clinical laboratory or imaging services) relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

(2)(i) A physician who orders/certifies home health services and the physician or, when permitted, other eligible professional who orders items of DMEPOS or clinical laboratory or imaging services is required to—

(A) Maintain documentation (as described in paragraph (f)(2)(ii) of this section) for 7 years from the date of the service; and

(B) Upon request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(2)(ii) of this section).

(ii) The documentation includes written and electronic documents (including the NPI of the physician who ordered/certified the home health services and the NPI of the physician or, when permitted, other eligible professional who ordered the items of DMEPOS or the clinical laboratory or imaging services) relating to written orders or certifications or requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

§ 424.535 [Amended]

■ 5. In § 424.535, paragraph (a)(10)(i) is amended by removing the parenthetical phrase “(as described in section 1866(j) of the Act)”.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance Program)

Dated: January 18, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 29, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–9994 Filed 4–24–12; 8:45 am]

BILLING CODE 4120–01–P