instruments are tailored to reflect the steps in each type of process, as well as the average time it takes to complete each process. The information collection will:

- Allow beneficiaries to directly provide feedback about the services they receive under the QIO program;
- Provide quality improvement data for QIOs to improve the quality of service delivered to Medicare beneficiaries; and
- Provide evaluation metrics for CMS to use in assessing performance of QIO contractors.

To achieve the above goals, information collection will include: Experience Survey: The Experience Survey will be administered via telephone and mail to beneficiaries/representatives after the Quality of Care (Medical Record Review) complaint/Immediate Advocacy/appeal case has been closed. The goal of the Experience Survey is to assess beneficiary overall and specific experiences with the BFCC QIOs. *Form Number:* CMS–10393 (OMB control number: 0938–1177); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 9,000; *Number of Responses:* 9,000; *Total Annual Hours:* 2,250. (For policy questions regarding this collection, contact Renee Graves-Dorsey at 410–786–7142.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Health Outcomes Survey Field Test; *Use:* CMS is required to collect and report quality and performance of Medicare health plans under provisions of the Social Security Act. Specifically, Section 1851(d) of the Act (Providing Information to Promote Informed Choice) requires CMS to collect data for MA plan comparison, including data on enrollee satisfaction and health outcomes, and report this information and other plan quality and performance indicators to Medicare beneficiaries prior to the annual enrollment period. The HOS meets the requirement for collecting and publicly reporting quality and other performance indicators, as HOS survey measures are incorporated into the Medicare Part C Star Ratings that are published each fall for consumers on the Medicare website.

This request is to conduct a field test with the goal of evaluating the measurement properties of new survey items, and the effects of new content and a web-based mode on response patterns and measure scores as compared to existing HOS survey items and protocols. Within each of the proposed field test protocol arms, there will be two versions of the questionnaire (see Attachments A and B) that will be identical except for slight differences in selected items where empirical data are needed to ascertain which of the two versions produces the best results (see Attachment C). The two versions of the questionnaire will test alternatives for selected new survey content that will potentially enhance and refine existing measures, allow CMS to develop new and methodologically simpler cross-sectional and longitudinal measures, expand on CMS's measurement of physical functioning and mental health, and add to CMS's efforts to measure and address health equity.

The data collected in this field test will be used by CMS to inform decisions on possible changes to HOS content and survey administration procedures. The items in the questionnaire reflect current health priorities and would provide CMS with data to study new longitudinal PROMs, cross-sectional measures, and enhancements to existing HOS measures for MA plans to use as a focus of their quality improvement efforts. Potential new measures derived from new HOS items will go through the Measures Under Consideration (MUC) process and rule-making before they are added to Star Ratings. *Form Number:* CMS–10861 (OMB Control Number: 0938–New); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 136; *Number of Responses:* 6,800; *Total Annual Hours:* 2,267. (For policy questions regarding this collection contact Kimberly DeMichele at 410–786–4286.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage; *Use:* Part D plan sponsors are required to issue the Notice of Denial of Medicare Prescription Drug Coverage notice when a request for a prescription drug or payment is denied, in whole or in part. The written notice must include a statement, in understandable language, the reasons for the denial and a description of the appeals process.

The purpose of this notice is to provide information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process. *Form Number:* CMS–10146 (OMB control number 0938–0976); *Frequency:* Daily; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 743; *Total Annual Responses:* 2,631,728; *Total Annual Hours:* 657,932. (For policy questions regarding this collection contact: Coretta Edmondson at 410–786–0512.)

Dated: October 24, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Registration Requirements in the 340B Drug Pricing Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS or Department).

ACTION: Notice.

SUMMARY: HRSA is issuing this Notice to inform and remind stakeholders of the registration requirements for off-site, outpatient hospital facilities to participate in the 340B Drug Pricing Program (340B Program). This Notice applies to all hospital types that participate in the 340B Program.

FOR FURTHER INFORMATION CONTACT: Questions should be directed to Michelle Herzog, Deputy Director, Office of Pharmacy Affairs, Office of Special Health Initiatives, HRSA, 5600 Fishers Lane, Room 8W12, Rockville, MD 20857, or by telephone at 301–594–4353.

SUPPLEMENTARY INFORMATION: Section 340B(a)(4) of the Public Health Service Act (PHS) Act (42 U.S.C. 256b) lists the various types of organizations (''covered entities'') eligible to participate in and benefit from the 340B Program. Section 340B(d)(2)(B)(i and ii) of the PHS Act requires the development of a system by which covered entities can attest to, and HRSA can verify, continued accuracy of information in the 340B database and compliance with 340B Program requirements. Section 340B(a)(9) of the PHS Act requires the Secretary to notify participating manufacturers of the identity of those organizations that meet the definition of covered entity under 340B(a)(4). Section 340B(d)(2)(B)(iv) of the PHS Act includes requirements for the establishment of a standardized

identification system whereby each covered entity site can be identified by manufacturers for purposes of facilitating the ordering, purchasing, and delivering of covered outpatient drugs. To fulfill these statutory requirements, all covered entities and their associated sites must be registered and listed in the 340B Office of Pharmacy Affairs Information System (OPAIS).

Section 340B(a)(4) of the PHS Act defines the types of entities eligible to participate in the 340B Program. Section 340B(a)(4)(L) states that a subset of Medicare disproportionate share hospitals (DSHs), as defined in section 1886(d)(1)(B) of the Social Security Act (SSA), are eligible for the 340B Program. Sections 340B(a)(4)(M–O) state that certain sole community hospitals, rural referral centers, critical access hospitals, children's hospitals, and free-standing cancer hospitals qualify for the 340B Program. Section 340B(a)(6) indicates that qualification of one part of an institution as a covered entity does not qualify all parts of the institution as a covered entity. With regard to hospital covered entities, HRSA published final guidelines on the participation of off-site, outpatient facilities in the 340B Program in the **Federal Register** at 59 FR 47884 (Sept. 19, 1994) and provided OPAIS registration instructions at *https://www.hrsa.gov/opa/registration.* To be registered and continue to be listed in OPAIS as participating in the 340B Program, a hospital covered entity's off-site, outpatient facility must (1) be listed as reimbursable on the hospital's most recently filed Medicare Cost Report and (2) have associated outpatient costs and charges on the most recently filed Medicare Cost Report, which is filed with the Centers for Medicare & Medicaid Services (CMS). This applies to all hospital types that are eligible for the 340B Program as outlined above. After being registered, if an off-site, outpatient facility is no longer reimbursable on the hospital's most recently filed Medicare Cost Report or if a facility no longer has outpatient costs and charges on the hospital's most recently filed Medicare Cost Report, then the facility is not eligible for participation in the 340B Program.

CMS regulations at 42 CFR 413.65 outline the standards for provider-based clinics that must be met for reimbursement purposes under the Medicare Program. Specifically, 42 CFR 413.65(e) provides a number of additional requirements that off-campus facilities or organizations must satisfy, including demonstrating a ''a high level of integration with the main provider.'' Approval of provider-based status requires submission of documentation demonstrating the off-campus facility's services are provided to the same patient population as the main provider. For all hospital types eligible to participate in the 340B Program, HRSA requires submission of the most recently filed Medicare Cost Reports, in order to ensure that off-site, outpatient facilities comply with 340B Program eligibility requirements. Specifically, to be considered eligible for the 340B Program, under HRSA's longstanding guidance (59 FR 47884, Sept. 19, 1994) an off-site, outpatient facility needs to be reimbursable on a hospital's most recently filed Medicare Cost Report. Because the 340B Program is by statute a discount drug purchasing program for covered outpatient drugs (see section 340B(a)(1) of the PHS Act), the hospital must indicate that the off-site, outpatient facility also has associated outpatient costs and charges as evidenced on the hospital's most recently filed Medicare Cost Report. To meet the statutory requirements at 340B(a)(9) and (d)(2)(B)(iv) of the PHS Act, the off-site, outpatient facility must also be listed in OPAIS.

As part of the government's efforts to respond to the unprecedented circumstances of the COVID–19 Public Health Emergency (PHE), HHS allowed various flexibilities across many of the Department's programs, including the 340B Program. In June 2020, the Frequently Asked Questions (FAQ) section of the Office of Pharmacy Affairs' COVID–19 resources web page announced the availability of a waiver of the requirement that off-site, outpatient facilities be (1) listed as reimbursable on the hospital's Medicare Cost Report prior to participating in the 340B Program; and (2) registered and listed in OPAIS prior to participating in the 340B Program. The FAQ stated that for those ''. . . hospitals who are unable to register their outpatient facilities because they are *not yet* [emphasis added] on the most recently filed Medicare Cost Report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity.''

The information on the COVID–19 resource web page reflected that the waiver was implemented in recognition of the need for hospitals to quickly respond to the rapidly evolving conditions of the COVID–19 pandemic and assist in creating efficiencies for hospitals to adjust operations in that response. For example, by providing hospitals the ability to quickly move a clinic from within the four walls of a hospital to outside the hospital to expand capacity for care for patients with COVID–19 while lessening the exposure risk for other patients needing access to outpatient care. The FAQ also recognized that during the COVID–19 public health emergency, hospitals had to transition certain clinic functions to meet the needs of the patients (*i.e.,* shift of an outpatient surgery center to an urgent care or emergency room) and prioritize care accordingly. As stated on the COVID–19 resources web page, HRSA encouraged hospitals to document these situations in their policies and procedures and reminded these covered entities of their responsibility to demonstrate compliance with all 340B Program requirements, including compliance with diversion and duplicate discounts, and ensure that auditable records are available for any 340B drugs dispensed to patients. As indicated in the FAQ, this waiver was only intended for off-site, outpatient facilities that would be listed as reimbursable on the hospital's future Medicare Cost Report.

Various HRSA program integrity efforts conducted since the start of the COVID–19 PHE have demonstrated that the waiver has added risk and complexity to HRSA's ability to effectively oversee ongoing compliance in the 340B Program. Further, the circumstances of COVID–19 are no longer rapidly evolving in a manner that requires significant unplanned activities or changes by hospital covered entities to accommodate these exigencies or adjust operations without planning for additional requirements to conduct business. The COVID–19 public health emergency ended on May 11, 2023, and hospitals have generally returned to regular operations.

Accordingly, HRSA has determined that ending the waiver is appropriate at this time given that, as described above, there are no longer exigent circumstances of a nationwide public health emergency that require allowing hospitals to expeditiously adjust their operations and locations for providing care off-site while maintaining immediate access to the 340B Program resources. By ending the waiver, HRSA will more effectively administer the program and support program integrity efforts. This Notice is being issued to provide clarity to stakeholders and provide a sufficient time period during which hospitals may take efforts to bring their operations into compliance. In ending this waiver, HRSA maintains its original policy goals in requiring certain criteria for off-site, outpatient facility registration on an ongoing basis. This includes:

• HRSA utilizes a hospital's most recent Medicare Cost Report filing to verify eligibility of off-site, outpatient facilities. As cited above, this is the standard that the 340B Program has used for decades, and it is HRSA's policy goal to maintain the continuity of the most recently filed Medicare Cost Report standard to determine hospital off-site, outpatient eligibility for the 340B Program. HRSA is unable to verify the eligibility of 340B Program participants when off-site, outpatient facilities are permitted to participate prior to their inclusion on the most recently filed Medicare Cost Report. Further, HRSA has a long-established standard of requiring not only the hospital, but the specific off-site, outpatient facility utilizing the discounts to be listed on the hospital's most recently filed Medicare Cost Report. This is to ensure that a hospital with multiple locations may only seek participation in and remain in the program for sites that meet all eligibility requirements.

• HRSA requires off-site, outpatient facilities to be registered and listed in OPAIS in alignment with the transparency provisions of the 340B statute at sections 340B(a)(9) and (d)(2)(B)(iv) of the PHS Act. When these facilities participate without first being registered and listed in OPAIS, as occurred under the waiver, it can create confusion and make efforts to audit or determine compliance difficult because HRSA, states, and drug manufacturers do not have uniform and comprehensive visibility into which sites are eligible to purchase 340B drugs. OPAIS is a centralized resource not just for HRSA, but also for manufacturers and states, who use it to plan operations (such as distribution) that may adjust depending on the number of facilities in a given location.

• Section 340B(a)(5)(A) of the PHS Act prohibits duplicate discounts in the 340B Program. This occurs when a manufacturer provides both a Medicaid rebate and a 340B discount on the same drug. HRSA's Medicaid Exclusion File (MEF) is a mechanism used to prevent duplicate discounts in Medicaid Fee-for Service for 340B drugs and serves as the official data source to determine whether 340B drugs are billed to Medicaid. The waiver increases the risk of duplicate discounts as unregistered sites cannot be listed on the MEF, as only sites registered and listed in OPAIS can be added to the MEF. Therefore, manufacturers and states would not know which sites use 340B for their Medicaid patients, as the MEF is used by them to decrease the likelihood of duplicate discounts. Requiring registration of sites to obtain access to 340B discounts on drugs may also decrease the risk of diversion that drugs would be dispensed to individuals for whom HRSA is unable to verify their patient eligibility status.

In addition to the foregoing policy goals, audits of covered entities suggest that the waiver is widely used by covered entities though it is no longer necessary to meet the unique challenges due to the unprecedented COVID–19 pandemic. For example, in FY 2023 audits of hospital covered entities, HRSA found that more than one-third of those hospital covered entities were using 340B drugs in unregistered sites, and those hospital covered entities reported that the unregistered sites would be listed on a future Medicare Cost Report. However, as of May 11, 2023, those off-site, outpatient facilities were not registered in OPAIS, causing significant challenges for HRSA to determine compliance for these participating sites, as it was unclear whether the unregistered sites would ever be eligible and an integral part of a 340B hospital. In that time period between the audits and May 11, 2023, hospitals should have been able to register offsite, outpatient facilities on OPAIS. Although these covered entities made representations to HRSA that those offsite, outpatient sites would be registered on the next filed Medicare Cost Report, HRSA has found that despite these representations, those covered entities did not attempt to bring those sites into compliance with HRSA requirements. As another example and as part of ongoing program integrity initiatives, HRSA recently engaged in risk-based program integrity efforts focused on hospitals that were at higher risk of compliance issues due to volume of purchases; number of off-site, outpatient sites; or prior audit findings. Specific to these efforts, HRSA sent letters in March 2023 to 60 hospitals containing a series of questions and information requests regarding program compliance, including the use of 340B drugs at off-site, outpatient facilities. Recipients of the letters included the 20 hospitals with the highest volume of purchases in the 340B Program, the 20 hospitals with the highest numbers of off-site, outpatient facilities in the 340B Program, and 20 additional covered entities that had other potential compliance risks. Based on analysis of Medicare Cost Report data, HRSA found that 27 of the 60 hospitals utilized 340B drugs at sites that were not listed on the most recently filed Medicare Cost Report. HRSA also found that some hospitals did not maintain that their offsite, outpatient facilities continued to have outpatient costs and charges on the most recently filed Medicare Cost Report. For sites that are using 340B drugs, but not listed on the hospital's most recently filed Medicare Cost Report, do not have associated outpatient costs and charges, or registered in OPAIS, HRSA cannot verify whether use of 340B drugs at those sites for patients is warranted, leading to possible diversion and duplicate discounts. Accordingly, HRSA determined that there is a need to verify off-site, outpatient facilities prior to their participation in the 340B program and on an on-going basis to ensure that they continue to meet 340B Program eligibility criteria.

HRSA's audit and other program integrity activities related to off-site, outpatient facilities highlight the increased 340B Program compliance risks associated with hospitals continuing to use a waiver that is no longer necessary. As some covered entities believed the waiver would continue indefinitely and would not be tied to the end of the PHE, HRSA is providing a transition period for covered entities to come into compliance with the off-site, outpatient facility registration requirements. This transition period will provide the opportunity for all hospitals to register, or take affirmative efforts to come into compliance with program requirements within an appropriate time. The burden of registration and including a facility in the next filed Medicare Cost Report does not take significant resources, and hospitals making good faith efforts to come into compliance should be able to adjust operations within this transition time period. Additionally, as was stated on the COVID–19 resources web page, HRSA encouraged hospitals to document situations in which the waiver was utilized and ensure that auditable records were available for any 340B drugs dispensed to patients. Accordingly, HRSA expects that the information needed for hospitals to register, or take affirmative efforts to come into compliance, should be readily available to affected hospital covered entities. HRSA will enforce its longstanding registration requirements as outlined below.

I. Transition Period for Registration of Off-Site, Outpatient Facilities

HRSA's approach to enforcement of 340B registration requirements will occur as follows:

1. HRSA will continue to allow off-site, outpatient facilities that are currently listed on the hospital's most recently filed Medicare Cost Report with

associated outpatient costs and charges, but that have not yet registered in OPAIS, to continue to use 340B drugs for patients of the covered entity pending registration of the facility in OPAIS during the next 340B Program quarterly registration period (January 1–16). If a facility is not registered during January 1–16 quarterly registration period, the hospital covered entity may be subject to audit and compliance action.

2. HRSA will continue to allow off-site, outpatient facilities that are not yet listed as a reimbursable facility on the hospital's most recently filed Medicare Cost Report with associated outpatient costs and charges to continue to use 340B drugs for patients of the covered entity if the following conditions are met:

a. The off-site, outpatient facility was opened and began using 340B drugs prior to the publication date of this Notice; and

b. The hospital that is the covered entity and the parent organization for the off-site, outpatient facility provides HRSA, via email to *340Bcompliance@hrsa.gov* within 90 days of publication date of this Notice, with the following information consistent with 340B registration requirements:

- The name of the off-site, outpatient facility;
- The date the site will be listed on the hospital's Medicare Cost Report (this must be the next filed Medicare Cost Report) with associated outpatient costs and charges; and
- The date the covered entity will register the site in OPAIS.

If a covered entity does not provide this information within 90-days of publication of this Notice, any off-site, outpatient facility that is not listed on the most recently filed Medicare Cost Report with associated outpatient costs and charges will have to cease purchasing 340B drugs for use at those facilities and will be subject to audit and compliance action. Consistent with longstanding 340B Program requirements, covered entities that provide this information within 90 days of publication must subsequently register in OPAIS at the soonest possible opportunity (and no later than the dates listed in the information provided to HRSA), and recertify in OPAIS annually with the most recently filed Medicare Cost Report with associated outpatient costs and charges.

3. Hospital covered entities using 340B drugs at off-site, outpatient facilities that are not listed on the most recently filed Medicare Cost Report with associated outpatient cost and charges, are not in OPAIS, and do not meet categories 1 or 2 above are out of compliance and must stop using 340B drugs at these unregistered sites as soon as practically possible, but no later than 90 days after the publication of this Federal Register Notice. After the 90-day grace period, non-compliant covered entities may be subject to audit and compliance action. HRSA is allowing for a 90-day grace period for affected hospitals to come into compliance and does not believe that any undue burden would be caused by reverting back to its original program guidelines, which have been in place since 1994.

II. Other Deadlines

Deadlines for 340B Program requirements other than those listed above are not affected by this Notice. All other registrations and change requests are not affected by this Notice and will be processed as they are received.

Carole Johnson,

Administrator.

[FR Doc. 2023–23702 Filed 10–26–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee Schedule of Meetings

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), HHS.

ACTION: Notice of meetings.

SUMMARY: The Health Information Technology Advisory Committee (HITAC) was established in accordance with the 21st Century Cures Act and the Federal Advisory Committee Act. The HITAC, among other things, identifies priorities for standards adoption and makes recommendations to the National Coordinator for Health Information Technology (National Coordinator). The HITAC will hold public meetings for the remainder of 2023 and throughout 2024. See list of public meetings below.

FOR FURTHER INFORMATION CONTACT: Michael Berry, Designated Federal Officer, at *Michael.Berry@hhs.gov,* (202) 701–0795.

SUPPLEMENTARY INFORMATION: Section 4003(e) of the 21st Century Cures Act (Pub. L. 114–255) establishes the Health Information Technology Advisory Committee (referred to as the ''HITAC''). The HITAC will be governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, (5 U.S.C. app.), which sets forth standards for the formation and use of federal advisory committees.

Composition: The HITAC is comprised of at least 25 members, of which:

- No fewer than 2 members are advocates for patients or consumers of health information technology;
- 3 members are appointed by the HHS Secretary
  - 1 of whom shall be appointed to represent the Department of Health and Human Services and
  - 1 of whom shall be a public health official;
- 2 members are appointed by the majority leader of the Senate;
- 2 members are appointed by the minority leader of the Senate;
- 2 members are appointed by the Speaker of the House of Representatives;
- 2 members are appointed by the minority leader of the House of Representatives;
- Other members are appointed by the Comptroller General of the United States.

Members serve for one-, two-, or three-year terms. All members may be reappointed for a subsequent three-year term. Each member is limited to two three-year terms, not to exceed six years of service. Members serve without pay but will be provided per-diem and travel costs for committee services, if warranted.

Recommendations: The HITAC recommendations to the National Coordinator are publicly available at *https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it.*

Public Meetings: All HITAC meetings will be virtual. Please note that some HITAC meetings may also have an in-person meeting option. For web conference instructions and the most up-to-date information, including in-person meeting location (if applicable), please visit the HITAC calendar on the ONC website, *www.healthit.gov/topic/federal-advisory-committees/hitac-calendar.*

The schedule of remaining meetings to be held in 2023 and throughout 2024 is as follows:

- November 9, 2023, from approximately 9:30 a.m. to 4:00 p.m./Eastern Time (virtual and in-person meeting options, address: Hubert H. Humphrey Federal Building, 200 Independence Ave SW, Washington, DC 20201)
- January 18, 2024, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time
- February 8, 2024, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time
- March 7, 2024, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time
- April 11, 2024, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time