eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations participating in the Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified EHR technology (CEHRT). These Recovery Act provisions, together with Title XIII of Division A of the Recovery Act, may be cited as the ''Health Information Technology for Economic and Clinical Health Act'' or the ''HITECH Act.''

The HITECH Act created incentive programs for EPs and eligible hospitals, including CAHs, in the Medicare Fee-for-Service (FFS), MA, and Medicaid programs that successfully demonstrate meaningful use of certified EHR technology. In their first payment year, Medicaid EPs and eligible hospitals could adopt, implement, or upgrade to certified EHR technology. It also allowed for negative payment adjustments in the Medicare FFS and MA programs starting in 2015 for EPs, eligible hospitals, and CAHs participating in Medicare that are not meaningful users of CEHRT. The Medicaid Promoting Interoperability Program did not authorize negative payment adjustments, but its participants were eligible for positive incentive payments.

In CY 2017, we began collecting data from eligible hospitals and CAHs to determine the application of the Medicare payment adjustments. At this time, Medicare eligible professionals no longer reported to the EHR Incentive Program, as they began reporting under the Merit-based Incentive Payment System (MIPS). This information collected was also used to make incentive payments to eligible hospitals and critical access hospitals in Puerto Rico.

In the FY 2019 IPPS/LTCH PPS Final Rule (83 FR 41634), we focused on reducing burden on eligible hospitals and CAHs. We finalized a new scoring methodology for eligible hospitals and CAHs, removing the requirement to report on and meet the threshold for all objectives and measures. This approach required an eligible hospital or CAH to meet the requirements on six measures, with scoring based on performance. This approach reduced burden by decreasing the amount of time needed to report on measures. Additionally, we finalized two new optional opioid measures and one new care coordination measure to help address the opioid epidemic and improve interoperability.

In the FY 2020 IPPS/LTCH Final Rule (84 FR 42591), we established the EHR Reporting Period to be a minimum of any continuous 90-day period in CY 2021 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program attesting to CMS, as well as finalizing the removal of the Electronic Prescribing Objective's Verify Opioid Treatment Agreement measure beginning with the EHR reporting period in CY 2020.

In the FY 2021 IPPS/LTCH PPS Final Rule (85 FR 58966), we are finalizing as proposed changes that we believe will continue to be a low reporting burden on eligible hospitals and CAHs in the Medicare Promoting Interoperability Program while incentivizing the advanced use of CEHRT to support health information exchange, interoperability, advanced quality measurement, and maximizing clinical effectiveness and efficiencies. These finalized changes include continuing an EHR reporting period of a minimum of any continuous 90-day period in CY 2022, and maintaining the Query of PDMP measure as optional and worth 5 bonus points in CY 2021.

In the FY 2022 IPPS/LTCH PPS Proposed Rule (86 FR 25628), we proposed changes that we believe will continue to be a low reporting burden on eligible hospitals and CAHs in the Medicare Promoting Interoperability Program while incentivizing the advanced use of CEHRT to support health information exchange, interoperability, advance quality measurement, and maximize clinical effectiveness and efficiencies. The proposals include continuing an EHR reporting period of a minimum of any continuous 90-day period in CY 2023, maintaining the Query of PDMP measure as optional but worth 10 bonus points in CY 2022, the addition of a new Health Information Exchange Bi-Directional Exchange measure beginning in CY 2022 as an optional alternative to the two existing measures, a requirement of reporting 4 specific Public Health and Clinical Data Exchange Objective measures, the inclusion of a new SAFER Guides measure attestation response, and to adopt two new eCQMs to the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2023 (in addition to removing three eCQMs from the measure set beginning with the reporting period in CY 2024, in alignment with the finalized changes to the Hospital IQR Program. In the FY 2022 IPPS/LTCH PPS Final Rule (86 FR 45460 through 45498), we finalized these proposals. We did not finalize a proposal to update the Provide Patients Electronic Access to their Health Information measure to include a data retention requirement; however, this proposal would not have affected our information collection burden estimate.

We note the previously approved PRA package under OMB control number 0938–1278 reflecting updates to information collection burden estimates based on policies finalized in the FY 2021 IPPS/LTCH PPS Final Rule include information collection burden estimates for 2021, which is the last year for including Medicaid eligible providers, eligible hospitals, and CAHs in the burden estimate as the Medicaid Promoting Interoperability Program concludes December 31, 2021. Therefore, this PRA request for information collection burden in 2022 does not include any burden under the Medicaid Promoting Interoperability Program. *Form Number:* CMS–10552 (OMB control number: 0938–1278); *Frequency:* Annually; *Affected Public:* State, Local or Private Government; Business and for-profit and Not-for-profit; *Number of Respondents:* 3,300; *Total Annual Responses:* 3,300; *Total Annual Hours:* 21,450. For policy questions regarding this collection, contact Jessica Warren at 410–786–7519.)

Dated: October 8, 2021.

William N. Parham, III,

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

[FR Doc. 2021–22448 Filed 10–13–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–372(S), CMS–10305, CMS–10148, CMS–10784, CMS–10715, CMS–10768, CMS–R–43 and CMS–10417]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of

information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *November 15, 2021.*

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Report on Home and Community Based Services Waivers and Supporting Regulations; *Use:* We use this report to compare actual data to the approved waiver estimates. In conjunction with the waiver compliance review reports, the information provided will be compared to that in the Medicaid Statistical Information System (MSIS) (CMS–R–284; OMB control number: 0938–0345) report and FFP claimed on a state's Quarterly Expenditure Report (CMS–64; OMB control number: 0938–1265), to determine whether to continue the state's home and community-based services waiver. States' estimates of cost and utilization for renewal purposes are based upon the data compiled in the CMS–372(S) reports. *Form Number:* CMS–372(S) (OMB control number: 0938–0272); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 48; *Total Annual Responses:* 253; *Total Annual Hours:* 11,132. (For policy questions regarding this collection contact Ralph Lollar at 410–786–0777.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(j)); *Use:* Sections 1857(e) and 1860D–12 of the Social Security Act (''the Act'') authorize CMS to establish information collection requirements with respect to MAOs and Part D sponsors. Section 1857(e)(1) of the Act requires MAOs to provide the Secretary of the Department of Health and Human Services (DHHS) with such information as the Secretary may find necessary and appropriate. Section 1857(e)(1) of the Act applies to Prescription Drug Plans (PDPs) as indicated in section1860D–12. Pursuant to statutory authority, CMS codified these information collection requirements in regulation at §§ 422.516(g) Validation of Part C Reporting Requirements, and 423.514(j) Validation of Part D Reporting Requirements respectively.

Data collected via Medicare Part C and Part D reporting requirements are an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of Medicare benefits to beneficiaries. CMS uses the findings collected through the data validation process to substantiate the data reported via Medicare Part C and Part D reporting requirements. Data validation provides CMS with assurance that plan-reported data are credible and consistently collected and reported by Part C and D SOs. CMS uses validated data to respond to inquiries from Congress, oversight agencies, and the public about Part C and D SOs. The validated data also allows CMS to effectively monitor and compare the performance of SOs over time. Validated plan-reported data may be used for Star Ratings, Display measures and other performance measures. Additionally, SOs can take advantage of the DV process to effectively assess their own performance and make improvements to their internal operations and reporting processes. *Form Number:* CMS–10305 (OMB control number: 0938–1115); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 761; *Total Annual Responses:* 761; *Total Annual Hours:* 20,945. (For policy questions regarding this collection contact Chanelle Jones at 410–786–8008.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form; *Use:* The Secretary of Health and Human Services (HHS), hereafter known as ''The Secretary,'' codified 45 CFR parts 160 and 164 Administrative Simplification provisions that apply to the enforcement of the Health Insurance Portability and Accountability Act of 1996 Public Law 104–191 (HIPAA). The provisions address rules relating to the investigation of non-compliance of the HIPAA Administrative Simplification code sets, unique identifiers, operating rules, and transactions. 45 CFR 160.306, Complaints to the Secretary, provides for investigations of covered entities by the Secretary. Further, it outlines the procedures and requirements for filing a complaint against a covered entity.

Anyone can file a complaint if he or she suspects a potential violation. Persons believing that a covered entity is not utilizing the adopted Administrative Simplification provisions of HIPAA are voluntarily requested to file a complaint with CMS via the Administrative Simplification Enforcement and Testing Tool (ASETT) online system, by mail, or by sending an email to the HIPAA mailbox at *hipaacomplaint@cms.hhs.gov.* Information provided on the standard form will be used during the investigation process to validate non-

compliance of HIPAA Administrative Simplification provisions.

This standard form collects identifying and contact information of the complainant, as well as the identifying and contact information of the filed against entity (FAE). This information enables CMS to respond to the complainant and gather more information if necessary, and to contact the FAE to discuss the complaint and CMS' findings. *Form Number:* CMS–10148 (OMB control number: 0938–0948); *Frequency:* Occasionally; *Affected Public:* Private sector, Business or Not-for-profit institutions, State, Local, or Tribal Governments, Federal Government, Not-for-profits institutions; *Number of Respondents:* 21; *Total Annual Responses:* 21; *Total Annual Hours:* 12. (For policy questions regarding this collection contact Cecily Austin at 410–786–0895.)

4. *Type of Information Collection Request:* New collection (Request for a new OMB control); *Title of Information Collection:* The Home Health Care CAHPS® Survey (HHCAHPS) Mode Experiment; *Use:* The reporting of quality data by HHAs is mandated by Section 1895(b)(3)(B)(v)(II) of the Social Security Act (''the Act''). This statute requires that ''each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause.'' HHCAHPS data are mandated in the Medicare regulations at 42 CFR 484.250(a), which requires HHAs to submit HHCAHPS data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. This collection of information is necessary to be able to test updates to the HHCAHPS survey and administration protocols.

CMS proposes to conduct a mode experiment with the main goal of testing the effects of a web-based mode on response rates and scores as an addition to the three currently approved modes (OMB Control Number: 0938–1370). The addition of a web mode will give HHAs an alternative or an addition to the use of mail and telephone modes. CMS is also interested in testing a revised, shorter version of the HHCAHPS survey, based on feedback from patients and stakeholders.

The data collected from the HHCAHPS Survey mode experiment will be used for the following purposes:

- Test the shortened survey instrument, including several new items;
- Compare survey responses across the four proposed modes to determine if adjustments are needed to ensure that data collection mode does not influence results; and
- Determine if and by how much patient characteristics affect the patients' rating of the care they receive and adjust results based on those factors.

The mode experiment is designed to examine the effects of the shortened survey on response rates and scores and to provide precise adjustment estimates for survey items and composites on the shortened survey instrument. Information from this mode experiment will help CMS determine whether an additional mode of administration (*i.e.,* Web data collection) should be included and a shortened survey instrument should be used in the current national implementation of the HHCAHPS Survey. *Form Number:* CMS–10784 (OMB control number: 0938-New); *Frequency:* Annually; *Affected Public:* Individuals or Households; *Number of Respondents:* 6,280; *Total Annual Responses:* 6,280; *Total Annual Hours:* 1,049. (For policy questions regarding this collection contact Lori E. Teichman at 410–786–6684.)

5. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Transparency in Coverage; *Use:* The final rules titled ''Transparency in Coverage,'' published November 12, 2020 (85 FR 72158), establish requirements for group health plans and health insurance issuers offering non-grandfathered coverage in the individual and group markets to disclose to a participant, beneficiary, or enrollee (or an authorized representative on behalf of such individual) the consumer-specific estimated cost-sharing liability for covered items or services from a particular provider, thereby allowing a participant, beneficiary, or enrollee to obtain an accurate estimate and understanding of their potential out-of-pocket expenses and to effectively shop for covered items and services. Plans and issuers are required to make such information available for covered items and services through an internet-based self-service tool, and, if requested, in paper form. The internet-based self-service tool must allow participants, beneficiaries, or enrollees to search for cost-sharing information for a covered item or service by inputting the name of a specific in-network provider in conjunction with a billing code or descriptive term, as well as other relevant factors such as location of service, facility name, or dosage. In addition, the final rules require that the tool allow the user to refine and reorder search results based on geographic proximity of in-network providers. For covered items and services provided by out-of-network providers, the tool must provide the out-of-network allowed amount, percentage of billed charges, or other rates that provide a reasonably accurate estimate of the amount a plan or issuer will pay by allowing consumers to input a billing code, descriptive code, or other relevant factor, such as location.

The final rules also require plans and issuers to publicly disclose applicable rates with in-network providers, including negotiated rates; historical data outlining the different billed charges and allowed amounts a plan or issuer has paid for covered items or services, including prescription drugs, furnished by out-of-network providers; and negotiated rates and historical net prices for covered prescription drugs furnished by in-network providers through three machine-readable files (an In-network Rate File, Allowed Amount File, and Prescription Drug File). The machine-readable files must be posted publicly on an internet website and updated on a monthly basis. *Form Number:* CMS–10715 (OMB control number: 0938–1372); *Frequency:* Frequently; *Affected Public:* Public and Private sectors; *Number of Respondents:* 908; *Total Annual Responses:* 74,460; *Total Annual Hours:* 28,618,546. (For policy questions regarding this collection contact Russell Tipps at 301–492–4371.)

6. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* The ESRD Network Peer Mentoring Program; *Use:* The End Stage Renal Disease (ESRD) Network Peer Mentoring Program is a voluntary program designed to provide patient peer support to people with kidney disease. In part, the peer support is beneficial because patients can give each other something most practitioners do not have: Lived experience with kidney disease. The support and perspective of someone who has ''been there'' can help people better cope with their circumstances.

The ESRD Network Peer Mentoring Program is a partnership between dialysis facilities, ESRD Networks, and patient peer mentors and mentees that wish to engage in the program. The peer mentoring program is organized and published with educational opportunities for peer mentors and mentees, provides resources, and includes a complementary toolkit for ESRD Networks and dialysis facilities to

promote and operationalize the program.

Program applicants are people with ESRD who: (1) Are adults over the age of 18; have been receiving in-center or home dialysis or have been transplanted for at least six months; actively engage in the care plan; consistently demonstrate leadership qualities at facility Quality Assurance & Performance Improvement (QAPI) meetings, Lobby Days, and other facility activities; and wish to be a peer mentor; or (2) are over 18 years of age; are newly diagnosed patients but have been on in-center dialysis for at least six months; are looking for peer support to help them transition to their new reality; and are known as a peer mentee.

To participate in the ESRD Network Peer Mentoring Program, peer mentors and mentees will complete an online application form stored in Confluence. The application serves to validate the peer mentor or peer mentee interest in the ESRD Network Peer Mentoring Program. Information collection is important to the process of pairing peer mentors and mentees with similarly lived experience and interests with their kidney disease. In addition, the application collects information about the peers' interest in kidney disease, treatment modality, age range, preferred gender recognition, and attitudes toward their kidney disease diagnosis. It also supports aligning hobbies, and genders to support best matched peers with each other. *Form Number:* CMS–10768 (OMB control number: 0938–NEW); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 75; *Total Annual Responses:* 75; *Total Annual Hours:* 19. (For policy questions regarding this collection, contact Lisa Rees at 816–426–6353.)

7. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Conditions of Coverage for Portable X-ray Suppliers and Supporting Regulations; *Use:* The requirements contained in this information collection request are classified as conditions of participation or conditions for coverage. Portable X-rays are basic radiology studies (predominately chest and extremity X-rays) performed on patients in skilled nursing facilities, residents of long-term care facilities and homebound patients. The CoPs are based on criteria described in the law, and are designed to ensure that each portable X-ray supplier has properly trained staff and provides the appropriate type and level of care for patients. The information collection requirements described below are necessary to certify portable X-ray suppliers wishing to participate in the Medicare program. There are currently 506 portable X-ray suppliers participating in the Medicare program.

On September 30, 2019 (84 FR 51732), CMS updated the personnel requirements for portable X-ray technicians at 42 CFR 486.104(a), to focus on the qualifications of the individual performing services removing school accreditation requirements and simplifying the structure of the requirements. Additionally, CMS also revised the requirements for referral of service at 42 CFR 486.106(a) for portable X-ray requirements for orders. This change removed the requirement that physician or non-physician practitioner's orders for portable X-ray services must be written and signed and replacing the specific requirements related to the content of each portable X-ray order with a cross-reference to the requirements at 42 CFR 410.32, which also apply to portable X-ray services. *Form Number:* CMS–R–43 (OMB Control number: 0938–0338); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 506; *Total Annual Responses:* 1,012; *Total Annual Hours:* 324. (For policy questions regarding this collection contact James Cowher at 410–786–1948.)

8. *Title of Information Collection:* Medicare Fee-for-Service Prepayment Review of Medical Records; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* The Medical Review program is designed to prevent improper payments in the Medicare FFS program. Whenever possible, Medicare Administrative Contractors (MACs) are encouraged to automate this process; however, it may require the evaluation of medical records and related documents to determine whether Medicare claims are billed in compliance with coverage, coding, payment, and billing policies. Addressing improper payments in the Medicare fee-for-service (FFS) program and promoting compliance with Medicare coverage and coding rules is a top priority for the CMS. Preventing Medicare improper payments requires the active involvement of every component of CMS and effective coordination with its partners including various Medicare contractors and providers. The information required under this collection is requested by Medicare contractors to determine proper payment, or if there is a suspicion of fraud. Medicare contractors request the information from providers/suppliers submitting claims for payment when data analysis indicates aberrant billing patterns or other information which may present a vulnerability to the Medicare program. *Form Number:* CMS–10417 (OMB control number: 0938–0969); *Frequency:* Occasionally; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 485,632; *Number of Responses:* 485,632; *Total Annual Hours:* 242,816. (For questions regarding this collection, contact Christine Grose at (410–786–1362).

Dated: October 8, 2021.

William N. Parham, III,

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

[FR Doc. 2021–22444 Filed 10–13–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6841]

Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of the draft guidance entitled ''Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff.'' This draft guidance explains that there are certain class I devices for which FDA does not intend to enforce Global Unique Device Identification Database (GUDID) submission requirements and describes how a labeler of a class I device can determine if its device is one of these devices in the revised section III of this draft guidance. When this draft guidance is finalized, the updates in section III of this draft guidance would supersede the recommendations in section III of the guidance ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking''