

Exchanges. Section 1311(c)(3) of the Patient Protection and Affordable Care Act directs the Secretary to develop a system to rate QHPs on the basis of quality and price and requires Exchanges to display this quality rating information on their respective websites. Section 1311(c)(4) of the Patient Protection and Affordable Care Act requires the Secretary to develop an enrollee satisfaction survey system to assess enrollee experience with each QHP (with more than 500 enrollees in the previous year) offered through an Exchange. Section 1311(h) requires QHPs to contract with certain hospitals that meet specific patient safety and health care quality standards.

This collection of information is necessary to provide adequate and timely health care quality information for consumers, regulators, and Exchanges as well as to collect information to appropriately monitor and provide a process for a survey vendor to appeal HHS' decision to not approve a QHP Enrollee Survey vendor application. *Form Number:* CMS-10520 (OMB control number: 0938-1249); *Frequency:* Annually; *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 264. *Total Annual Responses:* 264; *Total Annual Hours:* 348,764. For policy questions regarding this collection contact Nidhi Singh Shah at 301-492-5110. *Type of Information Collection Request:* Revision of a currently approved collection.

2. *Title of Information Collection:* State Agency Sheets for Verifying Exclusions from the Inpatient Prospective Payment System and Supporting Regulations—Rehabilitation Unit/Rehabilitation Hospital Criteria Worksheets; *Use:* The purpose of this information collection is to renew forms CMS-437A and 437B. Inpatient Rehabilitation Facility (IRF) hospitals and units must initially attest that they meet the Inpatient Prospective Payment System (IPPS) exclusion criteria set forth at 42 CFR 412.20 to 412.29 prior to being placed into IPPS exempt status. Form CMS-437A must be completed by IRF units and form CMS-437B must be completed by IRF hospitals.

For first time verification requests for exclusion from the IPPS, an IRF unit or hospital must notify the Regional Office (RO) servicing the State in which it is located that it believes it meets the criteria for exclusion from the IPPS. Currently, all new IRF units or hospitals must provide written certification that the inpatient population it intends to serve will meet the requirements of the

IPPS exclusion criteria for IRFs. The completed CMS-437A and 437B forms are submitted to the State Agency (SA) no later than 5 months before the date the IRF unit or hospital would become subject to Inpatient Rehabilitation Facility Prospective Payment System (IRF-PPS). For IRF units and hospitals already excluded from the IPPS, annual onsite re-verification surveys by the SA are no longer required. IRF units and hospitals must now re-attest to meeting the exclusion criteria every 3 years thereafter.

IRF units and hospitals that have already been excluded need not reapply for exclusion. These facilities will automatically be reevaluated yearly to determine whether they continue to meet the exclusion criteria. For the tri-annual re-verification, IRF units and hospitals will be provided with a copy of the appropriate CMS-437 worksheet at least 5-months prior to the beginning of its cost reporting period, so that the IRF unit or hospital official may complete and sign an attestation statement and complete and return the appropriate form CMS-437A or CMS-437B at least 5-months prior to the beginning of the cost reporting period. However, Fiscal Intermediaries (FIs) will continue to verify, on an annual basis, compliance with the 60 percent rule (42 CFR 412.29(b)(2)) for IRF units and hospitals through a sample of medical records and the SA will verify the medical director requirement.

The SA will notify the RO at least 60 days prior to the end of the IRF unit's or hospital's cost reporting period of the status of compliance or non-compliance with the payment requirements. The information collected on the 437A and 437B forms, along with other information submitted by the IRF is necessary for determining the IRF's IPPS exclusion status. *Form Number:* CMS-437A and CMS-437B (OMB control number: 0938-0986); *Frequency:* tri-annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 1,126; *Total Annual Responses:* 1,126; *Total Annual Hours:* 1,126. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

Dated: June 21, 2019.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-153, CMS-R-235, CMS-10439, CMS-10594, CMS-10328 and CMS-460]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by August 26, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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 <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

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

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

- ADDRESSES.**
- CMS-R-153 Medicaid Drug Use Review (DUR) Program
- CMS-R-235 Data Use Agreement (DUA) Form
- CMS-10439 Data Collection to Support Eligibility Determinations and Enrollment for Employers in the Small Business Health Options Program
- CMS-10594 Provider Network Coverage Data Collection
- CMS-10328 Medicare Self-Referral Disclosure Protocol
- CMS-460 Medicare Participation Agreement for Physicians and Suppliers

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently

approved collection; *Title of Information Collection:* Medicaid Drug Use Review (DUR) Program; *Use:* States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient profiles. These profiles must reflect at least the patient's name, address, telephone number, date of birth/age, gender, history, *e.g.*, allergies, drug reactions, list of medications, and pharmacist's comments relevant to the individual's drug therapy.

The States must conduct RetroDUR which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, inappropriate or medically unnecessary care. Patterns or trends of drug therapy problems are identified and reviewed to determine the need for intervention activity with pharmacists and/or physicians. States may conduct interventions via telephone, correspondence, or face-to-face contact.

Annual reports are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of States' DUR programs. The information submitted by States is reviewed and results are compiled by CMS in a format intended to provide information, comparisons, and trends related to States' experiences with DUR. States benefit from the information and may enhance their programs each year based on State reported innovative practices that are compiled by CMS from the DUR annual reports. *Form Number:* CMS-R-153 (OMB control number: 0938-0659); *Frequency:* Yearly, quarterly, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 663; *Total Annual Hours:* 41,004. (For policy questions regarding this collection contact Mike Forman at 410-786-2666.)

2. *Type of Information Collection Request:* Reinstatement with change of a currently approved collection; *Title of Information Collection:* Data Use Agreement (DUA) Form; *Use:* The Privacy Act of 1974 allows for discretionary releases of data maintained in Privacy Act protected systems of records under § 552a(b) (Conditions of Disclosure). The mandate to account for disclosures of data under the Privacy Act is found at § 552a(c)

(Accounting of Certain Disclosures). This section states that certain information must be maintained regarding disclosures made by each agency. This information is: Date, Nature, Purpose, and Name/Address of Recipient. Section 552a(e) sets the overall Agency Requirements that each agency must meet in order to maintain records under the Privacy Act.

The Data Use Agreement (DUA) form is needed as part of the review of each CMS data request to ensure compliance with the requirements of the Privacy Act for disclosures that contain PII. The DUA form also provides data requestors and custodians with a formal means to agree to the data protection and destruction statutory and regulatory requirements of CMS' PII data.

When entities, such as academic, federal or state agency researchers or CMS contractors request CMS PII/PHI data, they enter into a Data Use Agreement (DUA) with CMS. The DUA stipulates that the recipient of CMS data must properly protect the data according to all applicable data security standards and also provide for its appropriate destruction at the completion of the project/study or the expiration date of the DUA. The DUA form enables the data recipient and CMS to document the request and approval for release of CMS data. *Form Number:* CMS-R-235 (OMB control number: 0938-0734); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 9,200; *Total Annual Responses:* 9,200; *Total Annual Hours:* 2,900. (For policy questions regarding this collection contact Kari A. Gaare at 410-786-8612.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations and Enrollment for Employers in the Small Business Health Options Program; *Use:* Section 1311(b)(1)(B) of the Affordable Care Act directs that the SHOP assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Section 1311(c)(1)(F) of the Affordable Care Act directs HHS to establish criteria for certification of health plans as QHPs and plans to utilize a uniform enrollment form for qualified employers. Further, section 1311(c)(5)(B) directs HHS to develop a website that assists employers in determining if they are eligible to participate in SHOP. *Form Number:* CMS-10439 (OMB control number: 0938-1193); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits

institutions; *Number of Respondents*: 6,000; *Total Annual Responses*: 6,000; *Total Annual Hours*: 960. (For policy questions regarding this collection contact Michele Oshman at 410-786-4396.)

4. Type of Information Collection

Request: Extension without change of a currently approved collection; *Title of Information Collection*: Provider Network Coverage Data Collection; *Use*: The Affordable Care Act (ACA) established competitive private health insurance markets called Marketplaces, or Exchanges, which gave millions of Americans and small businesses access to affordable, quality insurance options that meet certain requirements. These requirements include ensuring sufficient choice of providers and providing information to enrollees and prospective enrollees on the availability of in-network and out-of-network providers. This information collection notice is for two of the standards from the HHS Notice of Benefit and Payment Parameters for 2017 (CMS-9937-F) final rule: One applying in the FFE and one applying to all QHPs. Specifically, under 45 CFR 156.230(d) and 156.230(e), we require notification requirements for enrollees in cases where a provider leaves the network and for cases where an enrollee might be seen by an out of network ancillary provider in in-network setting. These standards will help inform consumers about his or her health plan coverage to better make cost effective choices. The Centers for Medicare and Medicaid Services (CMS) is updating an information collection request (ICR) in connection with these standards. The burden estimates for this ICR included in this package reflects the additional time and effort for QHP issuers to provide these notifications to enrollees. *Form Number*: CMS-10594 (OMB control number: 0938-1302); *Frequency*: Yearly; *Affected Public*: Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents*: 470; *Total Annual Responses*: 356,260; *Total Annual Hours*: 194,250. (For policy questions regarding this collection contact Arunima Shukla at 410-786-5017.)\

5. Type of Information Collection

Request: Extension without change of a currently approved collection; *Title of Information Collection*: Medicare Self-Referral Disclosure Protocol; *Use*: Section 6409 of the ACA requires the Secretary to establish a voluntary self-disclosure process that allows providers of services and suppliers to self-disclose actual or potential violations of section 1877 of the Act. In addition, section 6409(b) of the ACA gives the Secretary

authority to reduce the amounts due and owing for the violations. To determine the nature and extent of the noncompliance and the appropriate amount by which an overpayment may be reduced, the Secretary must collect relevant information regarding the arrangements and financial relationships at issue from disclosing parties. The Secretary may also collect supporting documentation, such as contracts, leases, communications, invoices, or other documents bearing on the actual or potential violation(s). Most of the information and documentation required for submission to CMS in accordance with the SRDP is information that health care providers of services and suppliers keep as part of customary and usual business practices. *Form Number*: CMS-10328 (OMB control number: 0938-1106); *Frequency*: Yearly; *Affected Public*: Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents*: 470; *Total Annual Responses*: 356,260; *Total Annual Hours*: 194,250. (For policy questions regarding this collection contact Matthew Edgar at 410-786-0698.)

6. Type of Information Collection

Request: Extension without change of a currently approved collection; *Title of Information Collection*: Medicare Participation Agreement for Physicians and Suppliers; *Use*: Section 1842(h) of the Social Security Act permits physicians and suppliers to voluntarily participate in Medicare Part B by agreeing to take assignment on all claims for services to Medicare beneficiaries. The law also requires that the Secretary provide specific benefits to the physicians, suppliers and other persons who choose to participate. The CMS-460 is the agreement by which the physician or supplier elects to participate in Medicare. By signing the agreement to participate in Medicare, the physician, supplier, or their authorized official agrees to accept the Medicare-determined payment for Medicare covered services as payment in full and to charge the Medicare Part B beneficiary no more than the applicable deductible or coinsurance for the covered services. For purposes of this explanation, the term "supplier" means certain other persons or entities, other than physicians, that may bill Medicare for Part B services (e.g., suppliers of diagnostic tests, suppliers of radiology services, durable medical suppliers (DME) suppliers, nurse practitioners, clinical social workers, physician assistants). Institutions that render Part B services in their outpatient department are not considered

"suppliers" for purposes of this agreement. *Form Number*: CMS-460(OMB control number: 0938-0373); *Frequency*: Yearly; *Affected Public*: Private Sector (business or other for-profits); *Number of Respondents*: 29,000; *Total Annual Responses*: 29,000; *Total Annual Hours*: 7,250. (For policy questions regarding this collection contact Mark Baldwin at 410-786-8139.)

Dated: June 21, 2019.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-2223]

Clinical Investigations for Prostate Tissue Ablation 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 or Agency) is announcing the availability of the draft guidance entitled "Clinical Investigations for Prostate Tissue Ablation Devices." This draft guidance provides recommendations for clinical investigations for high intensity ultrasound systems for prostate tissue ablation and new types of prostatic tissue ablation devices. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by August 26, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal**: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are