and associated materials (see **ADDRESSES**).

CMS 10853 Patient Provider Dispute Resolution Requirements Related to Surprise Billing: Part II

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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Patient Provider Dispute Resolution Requirements Related to Surprise Billing: Part II; *Use:* The Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act provides Federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently.

The Act adds a new Part E of title XXVII of the Public Health Service Act establishing requirements applicable to providers, and facilities. These include provisions at new PHS Act sections 2799B–6 which requires providers and facilities to furnish a good faith estimate of expected charges upon request or upon scheduling an item or service for an individual. Providers and facilities are required to inquire if an individual is enrolled in a group health plan, group or individual health insurance coverage, a Federal Employees Health Benefits (FEHB) plan, or a Federal health care program and if enrolled in a group health plan, or group or individual health insurance coverage, or a health benefits plan under chapter 89 of title 5, whether the individual is seeking to have a claim for such item or service submitted to such plan or coverage (hereafter referred to as an ''uninsured (or self-pay) individual''). In the case that an uninsured (or self-pay) individual requesting a good faith estimate for an item or service or schedules an item or service to be furnished, PHS Act section 2799B–6(2)(B) and the October 2021 interim final rules at 45 CFR 149.610 require providers and facilities to furnish the good faith estimate to the uninsured (or self-pay) individual.

No Surprises Act section 112 also adds PHS Act section 2799B–7 as added by the interim final rules at 45 CFR 149.620 which directs the Secretary of HHS to establish a process under which an uninsured (or self-pay) individual can avail themselves of a patient-provider dispute resolution (PPDR) process if their billed charges after receiving an item or service are substantially in excess of the expected charges listed in the good faith estimate furnished by the provider or facility, pursuant to PHS Act section 2799B–6. This information collection request (ICR) focuses on the patient-provider dispute resolution process requirements under the October 2021 interim final rules (October 7, 2021, 86 FR 55980).

Dated: April 26, 2023.

William N. Parham, III,

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

[FR Doc. 2023–09198 Filed 5–1–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1874]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Perceptions of Prescription Drug Products With Medication Tracking Capabilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 1, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Perceptions of Prescription Drug Products with Medication Tracking Capabilities.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Perceptions of Prescription Drug Products With Medication Tracking Capabilities

OMB Control Number 0910–NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

The mission of the Office of Prescription Drug Promotion (OPDP) is to protect the public health by helping to ensure that prescription drug promotional material is truthful, balanced, and accurately communicated so that patients and health care providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and the characteristics of the disease and product impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how

understanding of prescription drug risks and benefits may vary as a function of audience. Our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area, advertising features.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our home page at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research,* which includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

Patient non-adherence to medication regimens is a well-known challenge in health care. The World Health Organization defines adherence as the extent to which a person's behavior—taking medication, following a diet, and/or executing lifestyle changes—corresponds with agreed recommendations from a health care provider (Ref. 1). It is estimated that only half of all patients with chronic health conditions take their medications as prescribed (Ref. 2), leading to as many as 100,000 preventable deaths and $100 billion in additional medical costs every year (Ref. 3). Numerous solutions have been tried to improve adherence, including resource-intensive approaches such as directly observed therapy, which entails a trained observer watching as the patient takes their medications (Ref. 4), and technology-supported tools for patients (*e.g.,* smartphone apps) (Ref. 5). As attention to the public health issue of medication adherence has grown, OPDP has noted a corresponding increase in the number of claims and presentations in prescription drug promotion that focus, either directly or through implication, on a product's potential to improve adherence to treatment regimens. Many of these presentations include information about options and capabilities available to help patients track their medication usage.

One avenue that prescription drug sponsors have begun exploring to track medication use includes the development of software that is disseminated by or on behalf of the drug sponsor and accompanies one or more of the sponsor's prescription drugs. This software is called prescription drug use-related software.[1] Studies exploring drug products with prescription drug use-related software have been conducted with medications to treat an array of chronic disorders, including psychiatric disorders (Ref. 6), uncontrolled type 2 diabetes (Ref. 7), end-stage renal disease requiring transplants (Ref. 8), and opioid use among patients with acute fractures (Ref. 9).

In recent years, new technologies that capture data on medication-taking behavior and drug administration have been employed. The SureClick 2.0 autoinjector for the prescription medication ENBREL, for example, has Bluetooth built into the white cap that covers the needle. The autoinjector records initial removal of the cap and can send this data via Bluetooth to a paired smartphone using a mobile app (Ref. 10). Technology can also now support the use of ingestible sensors embedded in pills that will emit a weak signal to a receiver (patch or lanyard) worn by the patient after the pill has been swallowed (Ref. 11). These data can then be transmitted to a paired mobile device and viewed by the patient through a smartphone app (Ref. 12). Whether these new technologies will have an impact on adherence is currently unknown.

Very little is known about patient and health care provider perceptions of products that track medication use or that work in tandem with software to track medication use, with most commentaries having been largely theoretical (Refs. 13 and 14). The focus of the present study is to explore patient and health care provider perceptions of a fictitious prescription drug product that is accompanied by software that is intended to track medication use.

We have the following specific questions:

Research Questions

1. When prescription drug promotional communications include claims about a product's ability to track medication use, do these claims influence perceptions about the product's risks and/or benefits (including its effect on medication adherence)?

2. If the promotional claims about the product's ability to track medication use are accompanied by a disclosure that describes what is known about the effect of medication tracking on medication adherence, does this have an influence on perceptions of the product's risks and/or benefits (including its effect on medication adherence)?

To complete this research, we propose the design in table 1, which varies based on:

- Whether the fictitious prescription drug product includes technology that tracks medication use;
- Whether the prescription drug promotional communication includes a disclosure describing what is known about the tracking technology's effect on medication adherence; and
- What the disclosure communicates about the tracking technology's effect on medication adherence (positive effect shown, no effect shown, or unknown effect).

TABLE 1—PROPOSED ONE-WAY, FIVE-LEVEL DESIGN (1 × 5)

Experimental condition	Claims about existence of medication tracking technology	Disclosure about technology's effect on adherence	Content of disclosure
1. Drug	No	No.	
2. Drug + medication tracking technology	Yes	No.	
3. Drug + medication tracking technology + no adherence data collected.	Yes	Yes	No data are available on the technology's effect on adherence.
4. Drug + medication tracking technology + data show no effect on adherence.	Yes	Yes	Data show the technology has no effect on adherence.

[1] In 2018, FDA established a public docket to solicit public comment on a proposed framework for regulating software applications disseminated by or on behalf of drug sponsors for use with one or more of their prescription drug products. See *https://www.federalregister.gov/documents/2018/11/20/2018-25206/prescription-drug-use-related-software-establishment-of-a-public-docket-request-for-comments.*

TABLE 1—PROPOSED ONE-WAY, FIVE-LEVEL DESIGN (1 × 5)—Continued

Experimental condition	Claims about existence of medication tracking technology	Disclosure about technology's effect on adherence	Content of disclosure
5. Drug + medication tracking technology + data show a positive effect on adherence.	Yes	Yes	Data show the technology has a positive effect on adherence.

Note: Condition 5 is the only condition in which an adherence benefit has been demonstrated for the fictitious product. The evidence required to support a medication adherence claim is not the focus of this study, and the evidence will not be described in the disclosure.
Condition 2 is a control because the drug product does include medication tracking technology, but the promotional communication does not include a disclosure about the technology's effect on medication adherence. Condition 1 is a true control because the drug product does not include medication tracking technology. Comparisons between conditions 1 and 2 will show us the baseline of this issue, *i.e.,* will indicate whether the fact that the drug product contains a tracking technology will alter perceptions of risks and benefits (including adherence).

We will conduct pretests with 50 consumers who self-identify as having been diagnosed with diabetes and 50 primary care physicians who treat diabetes (both obtained from a web-based research vendor) to ensure that the questionnaire programming works as expected. For the main study, we will then recruit 350 consumers who self-identify as having been diagnosed with diabetes and 350 primary care physicians who treat diabetes. Each participant will see one of five versions of a consumer web page for a fictitious prescription diabetes treatment, as reflected in table 1. They will answer a questionnaire designed to take no more than 20 minutes regarding their perception of the product's benefits, risks, and effect on adherence.

In the **Federal Register** of September 23, 2022 (87 FR 58103), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one submission that was not PRA-related (*regulations.gov tracking number lar–vv69–9wok*).

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

Activity	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Screener Consumers	680	1	680	.08 (5 minutes)	54.4
Screener Primary Care Physicians	680	1	680	.08 (5 minutes)	54.4
Pretest Consumers	50	1	50	.33 (20 minutes)	16.5
Pretest Primary Care Physicians	50	1	50	.33 (20 minutes)	16.5
Main Study Consumers	350	1	350	.33 (20 minutes)	115.5
Main Study Primary Care Physicians	350	1	350	.33 (20 minutes)	115.5
Total					372.8

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

* 1. World Health Organization, ''Adherence to Long-Term Therapies: Evidence for Action,'' p. 3, 2003, available at *https://apps.who.int/iris/handle/10665/42682,* accessed May 16, 2022.
2. Frias, J., N. Virdi, P. Raja, et al., ''Effectiveness of Digital Medicines to Improve Clinical Outcomes in Patients with Uncontrolled Hypertension and Type 2 Diabetes: Prospective, Open-Label, Cluster-Randomized Pilot Clinical Trial,'' *Journal of Medical internet Research,* Vol. 19, Issue 7, Article e246, 2017, doi:10.2196/jmir.7833.
3. Kleinsinger, F., ''The Unmet Challenge of Medication Nonadherence,'' *The Permanente Journal,* Vol. 22, Issue 3, Article 18–033, 2018, doi:10.7812/TPP/18–033.
4. Karumbi, J. and P. Garner, ''Directly Observed Therapy for Treating Tuberculosis,'' *Cochrane Database of Systematic Reviews,* Issue 5, Article CD003343, 2015, doi:10.1002/14651858.CD003343.pub4.
5. Dayer, L., S. Heldenbrand, P.O. Gubbins, et al., ''Smartphone Medication Adherence Apps: Potential Benefits to Patients and Providers,'' *Journal of the American Pharmacy Association (2003),* Vol. 53, Issue 2, pp. 172–181, 2013, doi:10.1331/JAPhA.2013.12202.
* 6. FDA, ''FDA Approves Pill with Sensor That Digitally Tracks If Patients Have Ingested Their Medication,'' FDA News Release, November 13, 2017, available at *https://www.fda.gov/news-events/press-announcements/fda-approves-pill-sensor-digitally-tracks-if-patients-have-ingested-their-medication,* accessed May 16, 2022.
7. Browne, S.H., Y. Behzadi, and G. Littlewort, ''Let Visuals Tell the Story: Medication Adherence in Patients with Type II Diabetes Captured by a Novel Ingestion Sensor Platform,'' *JMIR Mhealth Uhealth,* Vol. 3, Issue 4, Article e108, 2015, doi:10.2196/mhealth.4292.
8. Eisenberger, U., R.P. Wüthrich, A. Bock, et al., ''Medication Adherence Assessment: High Accuracy of the New Ingestible Sensor System in Kidney Transplants,'' *Transplantation,* Vol. 96, Issue 3, pp. 245–250, 2013, doi:10.1097/TP.0b013e31829b7571.
9. Chai, P.R., S. Carreiro, B.J. Innes, et al., ''Oxycodone Ingestion Patterns in Acute Fracture Pain with Digital Pills,'' *Anesthesia and Analgesia,* Vol. 125, Issue 6, pp. 2105–2112, 2017, doi:10.1213/ANE.0000000000002574.

* 10. Amgen Inc., ''Enbrel (etanercept): Highlights of Prescribing Information,'' revised April 2021, available at *https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/enbrel/enbrel_pi.pdf,* accessed May 16, 2022.
* 11. Reuter, E., '''Smart Pill' Startup EtectRx Strikes Partnership with Pear Therapeutics,'' *Med City News,* January 14, 2021, available at *https://medcitynews.com/2021/01/smart-pill-startup-etectrx-strikes-partnership-with-pear-therapeutics,* accessed May 16, 2022.
12. The Medical Futurist, ''The Present and Future of Digital Pills,'' July 21, 2020, available at *https://medicalfuturist.com/the-present-and-future-of-digital-pills,* accessed May 16, 2022.
13. George, C.E., ''Should a Psychiatrist Prescribe a Nanodrug to Help Parents Monitor a Teen's Adherence?,'' *AMA Journal of Ethics,* Vol. 21, Issue 4, Article e317–323, 2019, doi:10.1001/amajethics.2019.317.
* 14. Yang, M., ''A Psychiatrist's Perspective on the Digital Pill,'' *KevinMD.com,* December 2, 2017, available at *https://www.kevinmd.com/blog/2017/12/psychiatrists-perspective-digital-pill.html,* accessed May 16, 2022.

Dated: April 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09268 Filed 5–1–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0362]

A Risk-Based Approach to Monitoring of Clinical Investigations—Questions and Answers; Guidance for Industry; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 12, 2023. The document announced the availability of a final guidance entitled ''A Risk-Based Approach to Monitoring of Clinical Investigations—Questions and Answers; Guidance for Industry.'' The notice of availability for this final guidance was published with an incorrect OMB control number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Mona Shing, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3355, Silver Spring, MD 20993–0002, 301–796–0910.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 12, 2023 (88 FR 22038), in FR Doc. 2023–07687, the following correction is made:

1. On page 22040, in the first column, in the last sentence of ''II. Paperwork Reduction Act of 1995,'' the OMB control number 0910–0733 is corrected to read: ''. . .and the collections of information in FDA's guidance for industry entitled ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' have been approved under OMB control number 0910–0014.'' The correction changes the OMB control number from a number that was discontinued to an active one.

Dated: April 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09264 Filed 5–1–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1506]

Methodological Challenges Related to Patient Experience Data; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect comments on methodological challenges related to patient experience data in the context of the benefit-risk assessment and product labeling, and other areas of greatest interest or concern to public stakeholders. Public comments will help FDA plan two public workshops focused on methodological challenges and identify priorities for future work.

DATES: Although you can comment at any time, to ensure the Agency considers your comment in our development of the workshops, submit either electronic or written information and comments by July 3, 2023.

ADDRESSES: You may submit comments and information 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 solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–1506 for ''Methodological Challenges Related to Patient Experience Data.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the