

2024 for HOPDs and CY 2025 for ASCs. ASCs will continue with voluntary implementation of the OAS CAHPS Survey throughout CY 2024.

HOPDs and ASCs contract with a CMS-approved, independent third-party survey vendor to implement the survey on their behalf and to submit the OAS CAHPS data to CMS. CMS publicly reports comparative results from OAS CAHPS after each facility has conducted data collection for 4 quarters. Data from OAS CAHPS enable consumers to make more informed decisions when choosing an outpatient surgery facility, aid facilities in their quality improvement efforts, and help CMS monitor the performance of outpatient surgery facilities. Considering the increasing Medicare expenditures for outpatient surgical services from HOPDs and ASCs, the implementation of OAS CAHPS provides CMS with much-needed statistically valid data from the patient perspective to inform quality improvement and comparative consumer information about specific facilities. The information collected in the OAS CAHPS survey will be used for the following purposes:

- To provide a source of information from which patient experience of care measures can be publicly reported to beneficiaries to help them make informed decisions for outpatient surgery facility selection;
- To aid facilities with their internal quality improvement efforts and external benchmarking with other facilities; and
- To provide CMS with information for monitoring and public reporting purposes.

Form Number: CMS–10500 (OMB control number: 0938–1240); *Frequency:* Once; *Affected Public:* Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 2,534,643; *Total Annual Responses:* 2,534,643; *Total Annual Hours:* 614,976. (For policy questions regarding this collection contact Memuna Ifedirah at 410–786–6849).

2. Type of Information Collection Request: Revision with change of the previously approved collection; *Title of Information Collection:* Collection of Encounter Data from MA Organizations, Section 1876 Cost HMOs/CMPs, MMPs, and PACE Organizations; *Use:* Section 1853(a)(3)(B) of the Act directs CMS to require MA organizations and eligible organizations with risk-sharing contracts under 1876 to “submit data regarding inpatient hospital services ... and data regarding other services and other information as the Secretary deems necessary” in order to implement a methodology for “risk adjusting”

payments made to MA organizations and other entities. Risk adjustments to enrollee monthly payments are made in order to take into account “variations in per capita costs based on [the] health status” of the Medicare beneficiaries enrolled in an MA plan.

CMS uses encounter data to develop individual risk scores for risk adjusted payment to MA organizations, PACE organizations, and MMPs. Starting with Payment Year (PY) 2016, CMS began to blend risk scores calculated with Risk Adjustment Processing Data and Medicare Fee- For-Service (FFS) data with risk scores calculated with encounter data and FFS data, for risk scores calculated under both the CMS–HCC and the RxHCC models. In PY 2022, we will move to calculating risk scores under both the CMS–HCC and the RxHCC models using 100 percent of the risk score calculated using encounter data and FFS data.

All organizations required to submit encounter data use an electronic connection between the organization and CMS to submit encounter data and to receive information in return. CMS collects the data from MA organizations, 1876 Cost Plans, MMPs and PACE organizations in the X12N 837 5010 format for professional, DME, and institutional, and dental services or items provided to MA enrollees. *Form Number:* CMS–10340 (OMB control number: 0938–1152); *Frequency:* Daily; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 284; *Total Annual Responses:* 1,467,645,179; *Total Annual Hours:* 48,936,279. (For policy questions regarding this collection contact Raymond Mierwald at 410 446–5449).

Dated: November 28, 2023.

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 Identifiers: CMS–10525]

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 January 2, 2024.

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, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

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:* Extension of a currently approved collection; *Title of Information Collection:* Programs of All-Inclusive Care for the Elderly (PACE) PACE Quality Data Monitoring and Reporting; *Use:* The Programs of All-Inclusive Care for the Elderly (PACE) program is a unique model of managed care service delivery for the frail elderly, most of whom are dually-eligible for Medicare and Medicaid benefits. To be eligible to enroll in PACE, an individual must: be 55 or older, live in the service area of a PACE organization (PO), need a nursing home-level of care (as certified by the state in which he or she lives), and be able to live safely in the community with assistance from PACE.

PACE organizations are responsible for providing all required Medicare and Medicaid covered services, and any other service that the interdisciplinary team (IDT) determines necessary to improve and maintain a participant's overall health condition (42 CFR 460.92). POs must also comply with the quality monitoring and reporting requirements outlined in §§ 460.140, 460.200(b)(1), 460.200(c) and 460.202. POs are also required to report certain unusual incidents to other Federal and State agencies consistent with applicable statutory or regulatory requirements (see 42 CFR 460.136(a)(5)). *Form Number:* CMS-10525 (OMB control number: 0938-1264); *Frequency:* Occasion; *Affected Public:* Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 152; *Total Annual Responses:* 1,279; *Total Annual Hours:* 1,471. (For policy questions regarding this collection contact Donna Williamson at 410 786 4647.)

Dated: November 28, 2023.

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-2014-N-1051]

Modified Risk Tobacco Product Application: Renewal Applications for General Snus Smokeless Tobacco Products Submitted by Swedish Match U.S.A., Inc.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity to provide public comment on modified risk tobacco product applications (MRTPAs). The applications are for renewal of existing modified risk tobacco product (MRTP) orders for *General Snus* smokeless tobacco products submitted by Swedish Match U.S.A., Inc.

DATES: Electronic or written comments on the application may be submitted beginning December 1, 2023. FDA will establish a closing date for the comment period as described in section I.

ADDRESSES: You may submit comments 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-2014-N-1051 for "Modified Risk Tobacco Product Applications: Renewal applications for *General Snus* smokeless tobacco products submitted by Swedish Match U.S.A., Inc." 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 claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read the background documents or electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the