PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

	Inclusion criteria	Exclusion criteria
Timing	• Psychological flexibility (*e.g.,* AFQ–Y, AAQ). • Healthcare utilization. • A minimum of 4 weeks since the beginning of the intervention or baseline assessment (if the intervention start cannot be determined) for all outcomes except for harms. • We will extract harms reported at any followup, regardless of the duration since the intervention start or baseline assessment.	Mid-intervention assessment times.
Setting	KQ 1–3 • Administered in outpatient health care or community settings (*e.g.,* schools, residential). • Trials conducted in countries rated as ''very high'' on the 2019 Human Development Index (as defined by the United Nations Development Program).	In-patient, ED/EMS, and psychiatric subacute settings (*e.g.,* partial hospitalization programs, intensive outpatient programs).
Study Design	• Randomized controlled trials (individually or site-randomized), with individually randomized trials reporting outcomes for a minimum of 10 participants per treatment arm. • Period 1 data from crossover RCTs. • Published in English-language. • Published in 2010 or later.	Other study designs.

Abbreviations: AAQ = Acceptance and Action Questionnaire; AFQ–Y = Avoidance and Fusion Questionnaire for Youth; BDI = Beck Depression Inventory; BRIEF = Behavior Rating Inventory of Executive Function; CAIS = Child Anxiety Impact Scale; CAMM = Child and Adolescent Mindfulness Measure; CBCL = Child Behavior Checklist; CCSC = Children's Coping Strategies Checklist; CDI = Children's Depression Inventory; CDRS–R = Children's Depression Rating Scale–Revised; CES–D = Center for Epidemiologic Studies Depression Scale; CGAS = Children's Global Assessment Scale; CGI–I = Clinical Global Impression-Improvement Scale; CHQ = Child Health Questionnaire; CSI–CA = Coping Strategies Inventory for Children and Adolescents; ED/EMS = emergency department/emergency medical services; ECBI = Eyberg Child Behavior Inventory; FDI = Functional Disability Inventory Child Form; GAD–7 = Generalized Anxiety Disorder scale; HRV = heart rate variability; ITQOL = Infant/Toddler Quality of Life Questionnaire; KQ = Key Question; MASC = Multidimensional Anxiety Scale for Children; MFQ = Mood and Feelings Questionnaire; NA = not applicable; PedsQL = Pediatric Quality of Life Inventory; PHQ–A = Patient Health Questionnaire for Adolescents; PICOTS = population, interventions, comparators, outcomes, timing, and setting; PI–ED = Paediatric Index of Emotional Distress; PQ–LES–Q = Perceived Quality of Life Scale; RADS = Reynolds Adolescent Depression Scale; RSQ = Responses to Stress Questionnaire; SCARED = Screen for Child Anxiety Related Emotional Disorders; SCAS = Spence Children's Anxiety Scale; SCL = Skin Conductance Level; SDQ = Strengths and Difficulties Questionnaire; SLSS = Students' Life Satisfaction Scale; SSIS = Social Skills Improvement System; PANAS–C = Positive and Negative Affect Schedule for Children; SWLS = Satisfaction with Life Scale; VABS = Vineland Adaptive Behavior Scales; WIAT = Wechsler Individual Achievement Test; WISC = Wechsler Intelligence Scale for Children.

[a] These are reviewed in other AHRQ systematic reviews.

[b] We defined behavioral interventions as nonpharmacologic strategies intended to enhance outcomes by modifying behavior and/or ways of thinking (*e.g.,*cognitive behavioral therapy, coping skills training, behavioral therapy, biofeedback, dialectical behavioral therapy).

Dated: June 27, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–14573 Filed 7–1–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10849 and CMS–10516]

Agency Information Collection Activities: Proposed Collection; 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 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 September 3, 2024.

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, 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 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**).

CMS–10849—Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request

CMS–10516—Program Integrity: Exchange, Premium Stabilization

Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rule 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 Collections

1. Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request; *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (''the Act''). The Act establishes the Negotiation Program to negotiate maximum fair prices (''MFPs''), defined at 1191(c)(3) of the Act, for certain high expenditure, single source selected drugs covered under Medicare Part B and Part D. For the second year of the Negotiation Program, the Secretary of Health and Human Services (the ''Secretary'') will select up to 15 high expenditure, single source drugs covered under Part D for negotiation.

Negotiation Data Elements: The statute requires that CMS consider certain data from Primary Manufacturers as part of the negotiation process. To the extent that more than one entity meets the statutory definition of manufacturer (specified in section 1193(a)(1) of the Act) for a selected drug for purposes of initial price applicability year 2027, CMS will designate the entity that holds the New Drug Application(s) (NDA(s))/Biologics License Application(s) (BLA(s)) for the selected drug to be ''the manufacturer'' of the selected drug (hereinafter the ''Primary Manufacturer''). The Primary Manufacturer's data submissions include non-FAMP and related data for selected drugs for the purpose of establishing a ceiling price, as outlined in section 1193(a)(4)(A) of the Act, and the negotiation factors outlined in section 1194(e)(1) of the Act for the purpose of formulating offers and counteroffers process pursuant to section 1193(a)(4)(B) of the Act. Some of these data are held by the Primary Manufacturer and are not currently available to CMS. Data described in sections 1194(e)(1) and 1193(a)(4) of the Act must be submitted by the Primary Manufacturer.

Section 1194(e)(2) of the Act requires CMS to consider certain data on selected drugs and their alternative treatments. Because the statute does not specify where these data come from, CMS will allow for optional submission from Primary Manufacturers and the public. CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in section 1194(e)(2) of the Act. Manufacturers may optionally submit this information as part of their Negotiation Data Elements Information Collection Request Form. The public may also optionally submit evidence about the selected drugs and their alternative treatments.

Drug Price Negotiation Process: Any MFPs that are negotiated for these selected drugs will apply beginning in initial price applicability year 2027. For initial price applicability year 2027, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into a Medicare Drug Price Negotiation Program Agreement or February 28, 2025.

Section 1194(b)(2)(C) of the Act provides that if the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer may submit an optional written counteroffer no later than 30 days after the date of receipt of CMS' written initial offer. If the Primary Manufacturer chooses to develop and submit a written counteroffer to CMS' written initial offer during the drug price negotiation process for initial price applicability year 2027, the Primary Manufacturer must submit the Counteroffer Form. CMS is also considering expanded use of the Counteroffer Form within the drug price negotiation process. *Form Number:* CMS–10849 (OMB control number: 0938–1452); *Frequency:* Once; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 340; *Number of Responses*: 340; *Total Annual Hours:* 16,264. (For policy questions regarding this collection contact Elisabeth Daniel at 667–290–8793.)

2. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rule II; *Use:* On March 23, 2010, the Patient Protection and Affordable Care Act (PPACA; Pub. L. 111–148) was signed into law and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was signed into law. The two laws implement various health insurance policies. On June 19, 2013, the Department of Health and Human Services (HHS) published proposed rule CMS–9957–P: Program Integrity: Exchanges, SHOP, Premium Stabilization Programs, and Market Standards (78 FR 37302) (Program Integrity Proposed Rule) which, among other things, contained third party disclosure requirements and data collections that supported the oversight of premium stabilization programs, State Exchanges, and qualified health plan (QHP) issuers in Federally-facilitated Exchanges (FFEs). Parts of the proposed rule were finalized as Patient Protection and Affordable Care Act; Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rule (Program Integrity Final Rule II), 78 FR 25326 (October 24, 2013). This ICR relates to a portion of the information collection request (ICR) requirements set forth in the final rule. *Form Number:* CMS–10516 (OMB control number: 0938–1277); *Frequency:* Annually; *Affected Public:* Private Sector, State, Local, or Tribal Governments; Business or other for-profits, and Not-for Profits; *Number of Respondents:* 457; *Number of Responses*: 457; *Total Annual Hours:* 42,771. (For questions regarding this collection, contact Andrea Honig at (301) 492–4147.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–14582 Filed 7–1–24; 8:45 am]

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