Centers for Medicare and Medicaid Services Response to Public Comments Received for CMS-10849, OMB 0938-1452

Negotiation Data Elements

Instructions for Sections A through G

Comment: A couple of commenters provided insight into their experience using the CMS Health Plan Management System ("the CMS HPMS") to submit data and provided recommendations to reduce burden on utilizing the system. Such suggestions included standardization of field names, bulk upload templates, and export functionality. A commenter provided recommendations to improve the submission process, including timely notifications for refiling data, submission templates, and simplification of data requests. A commenter suggested that respondents should be able to include an executive summary in submissions to present their submissions succinctly and stated that doing so would minimize CMS' burden reviewing and processing the information. A commenter proposed methodological changes to the ICR such as the ability for a manufacturer to submit a crosswalk for its dossier that matches dossier content to ICR question 43, and supplemental submission for non-manufacturers through which information related to ICR questions 60 and 61 can be provided.

Response: CMS appreciates the commenters sharing their experience with data submission and recommendations. CMS continues to identify opportunities to apply lessons learned and to improve this ICR, including by considering respondent feedback and suggestions. CMS appreciates the suggestions brought forward by commenters on potential submission options and will consider these suggestions for future updates. However, in order to continue to meet statutory timing requirements, CMS will not adopt these suggestions at this time. Manufacturers and other interested parties have been able to make successful submissions in the current system, which indicates that the current approach is effective. CMS reminds interested parties that it provides technical assistance throughout the ICR submission process if a Primary Manufacturer has questions about this ICR and/or the CMS HPMS.

Section C: Research and Development (R&D) Costs and Recoupment

Comment: A couple of commenters suggested that manufacturers be allowed to include R&D costs from failed candidates and from all indications of the selected drugs. Inclusion of such costs would support ongoing drug development.

Response: CMS thanks these commenters for their feedback. Consistent with our response in the Negotiation Program Guidance, CMS declines to revise the definitions for R&D costs beyond these changes because CMS believes the information included in the definitions is consistent with the statutory intent to collect "research and development costs of the manufacturer for the drug" as specified in section 1194(e)(1)(A) of the Act.

Section F: Patents, Exclusivities, and Approvals

Comment: A few commenters provided suggestions to revise the data collected about patents, exclusivities, and approvals in Section F. One commenter stated that requests for patent information related to the selected drug are overbroad, ambiguous, and contradict the constitutional framework that is intended to protect and encourage innovation. This commenter requested that CMS narrow the patent information required under Section F to only those patents necessary to provide contextual information about the selected drug for purposes of the negotiation process. One commenter maintained its previous position that it is inappropriate for CMS to require manufacturers to identify "composition of matter" patents in their reporting because all patents must be new, useful, and non-obvious and therefore should be considered equally by CMS, and it is unclear how this new requirement would be relevant to negotiating an MFP.

Response: We thank the commenters for their feedback. We believe the information requested in Section F is consistent with the statutory requirement to collect data on "pending and approved patent applications, exclusivities recognized by the [FDA], and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for the drug" as specified in section 1194(e)(1)(D) of the Act. We believe that asking Primary Manufacturers to identify "composition of matter" patents is consistent with and relevant to our consideration of data as required by section 1194(e)(1)(D) of the Act.

Comment: Some commenters requested that CMS remove question 12, stating that loss of exclusivity is dictated by a range of factors that are beyond the manufacturer's control, difficult to predict, and that the question will increase manufacturer burden without improving CMS' ability to accurately assess the selected drug. A couple of commenters raised concerns that sharing this information could create significant legal, commercial, and confidentiality risks by compromising future patent strategies, anticipated litigation outcomes, or settlement positions. A couple of commenters stated that it is unclear how CMS intends to use this information in negotiations and requested that CMS provide clarity. A couple of commenters stated that while some public documents, such as a Form 10K filing pursuant to section 13 or 15(d) of the Securities and Exchange Act of 1934, may provide estimates of loss of exclusivity for other purposes, they do not represent a comprehensive "best estimate' of the date of generic or biosimilar entry, and the relevance of those estimates to pricing of a selected product has not been demonstrated.

Response: We appreciate the feedback. Information about predicted loss of exclusivity is relevant to evaluating Primary Manufacturer's concerns about the impact of an MFP on their business, and is a foundational element to understanding the market in the U.S. We acknowledge that loss of exclusivity is dictated by a range of factors but note that question 12 directs Primary Manufacturer's to provide and explain a "best estimate" for loss of exclusivity. Additionally, we believe question 12 provides sufficient guidance on what information a Primary Manufacturer may choose to include in providing and explaining such best estimate.

In response to the concerns about legal, commercial, and confidentiality risk of sharing information on predicted loss of exclusivity, we refer readers to section 1193(c) of the Act and

42 CFR 429.300(a) and (b), which establish that information deemed proprietary will only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. We would deem proprietary information, including trade secrets and confidential commercial or financial information, as confidential information exempt from disclosure if the information meets the requirements set forth under Exemption 3 or Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(3), (4)).

Section G: Market Data and Revenue and Sales Volume Data

Comment: A few commenters opposed the proposed changes to the ICR. A couple of commenters questioned the justification for the newly added payer category breakdowns. At the same time, they noted that CMS decreased the character limits for some narrative responses, which causes manufacturers to spend more time condensing complex technical information rather than reducing their overall workload. They recommend that CMS eliminate the global revenue requirement, remove the new payer mix estimation requirement, restore the character limits that were decreased, and improve transparency around how submitted data is used.
A few commenters requested the removal of question 27. They noted that the payer mix and indication-level information requested in question 27 is a substantial burden to produce and CMS did not clearly explain why it is necessary for the negotiation process. In addition, due to the complexity involved with identifying payers, reported data could result in misleading conclusions.

Response: CMS thanks these commenters for their feedback. Based on experience thus far, CMS determined that additional information was needed to ensure a holistic evaluation of the selected drug. For example, payer mix is core to understanding 1194(e)(1)(E) market pricing data in the US. CMS believes this additional information is a low burden for manufacturers as this information is estimated in the ordinary course of business. In response to comments regarding Question 27, CMS is removing Question 27b, removed “Manufacturer-run patient assistance” as a payer type in Question 27a, and revised the remaining payer types to simplify the level of granularity. Question 27c is now revised to be 27b and prompts manufacturers to describe assumptions, methodologic steps, and other information relied on to provide the responses to Question 27a.

CMS reduced the maximum character limit for certain questions in Section I as part of CMS’ ongoing effort to identify opportunities to streamline this ICR. CMS found that some respondents duplicate information across certain questions, which may increase respondents’ response burden in preparing and responding to this ICR, along with CMS’ internal review burden due to the duplicate information. CMS believes the proposed character limits available are adequate to address the questions. However, CMS notes that the ICR maintains the larger number of characters permitted for a number of questions.

Comment: A commenter noted potential confusion with the wording in Section G of the ICR: "If an NCPDP BUS of EA is used, one EA must represent a single individual dosage form or dispensable unit (e.g., one tablet, capsule, vial, syringe, inhaler, or patch) and should match what is reported in Section A." The inclusion of inhaler in the examples may lead to confusion as dry

powder inhalers use a billing unit of pre-metered blisters instead of inhalers. They recommended removing the parenthetical examples or remove the word inhaler from the list of examples.

Response: CMS thanks this commenter for sharing their insight. The word "inhaler" was removed from the list of examples. In addition, instructions for Question 14 include a request to specify the units that one EA represents if the NCPDP BUS of EA is used.

Comment: A few commenters expressed concern that certain sections of the ICR request proprietary pricing information — such as Federal Supply Schedule prices and payer mix breakdowns — that goes beyond what the law requires and could expose commercially sensitive business data. A commenter encouraged strengthening confidentiality protections.

Response: CMS thanks the commenters for their feedback. Section 1194(e) of the Act authorizes CMS to collect confidential commercial and financial information from manufacturers for the purpose of negotiating the MFP of a selected drug. Specifically, section 1194(e)(1)(E) of the Act provides that "market data and revenue and sales volume data for the drug in the United States" is in scope. CMS understands that the specific data elements mentioned by commenters are inclusive in this statutory authorization.

With regards to the comment regarding confidentiality protections, consistent with our responses in the revised guidance for initial price applicability years 2026, 2027, and 2028, section 1193(c) of the Act requires that information submitted to CMS by the manufacturer of a selected drug that is proprietary information, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. CMS is committed to protecting confidential and proprietary information obtained from manufacturers throughout the negotiation process. CMS refers to § 429.300 of this final rule for further details regarding the confidentiality policy.

Section I: Evidence about Alternative Treatments

Comment: A couple of commenters opposed the inclusion of Question 30 and asked that CMS remove or revise the question stating that the request to identify if the respondent is "affiliated with the manufacturer of the selected drug or its potential therapeutic alternative(s)" may be confusing or otherwise dissuade stakeholders from responding to the ICR. One commenter stated that a manufacturer could inform stakeholders, such as a patient advocacy organization or medical professional society, about the ICR without meaning to ask them to respond to the ICR. One commenter supported the inclusion of Question 30 and asked that CMS also require the disclosure of relevant financial relationships with manufacturers of the selected drug or its therapeutic alternative(s), including indirect support.

Response: We thank the commenters for their feedback. Consistent with CMS' response to similar comments received in response to the initial price applicability year 2027 and 2028 versions of this ICR, we reiterate that we will review all submitted information. We believe information regarding relationships with manufacturers is important to promote transparency in the negotiation process. We believe that Question 30 provides sufficient information on a respondent's relationship with the manufacturer of the selected drug or a therapeutic alternative(s). We refer interested parties to §§ 429.520 and 429.525 regarding how information

provided in response to Section I is used in the development of the initial offer and concise justification.

General Instructions for Section I

Comment: A couple of commenters opposed the reduction of character limits in various questions in Section I stating that reduced character limits will limit the amount and types of information available to CMS. Similarly, a couple of commenters opposed the revision to combine questions on unmet medical need and therapeutic advance when such topics were previously addressed separately stating that by combining these questions limits the amount of information that can be provided to CMS. A commenter supported the combination of certain questions in the ICR for the purpose of streamlining, including the questions regarding unmet medical need and therapeutic advance.

Response: We thank commenters for their feedback. Based on our review of responses received in previous submissions for initial price applicability years 2027 and 2028, we found that information submitted in response to the separate questions regarding therapeutic advance and unmet need in the previous versions of this ICR were often duplicative. We believe that these questions could be combined while maintaining the opportunity for a respondent to provide information about each of these aspects of a selected drug and its potential therapeutic alternative(s). In an effort to streamline the information requested in this ICR, CMS combined these questions.

Patient or Caregiver-Focused Input

Comment: A commenter requested that CMS retain questions concerning treatment risks.

Response: We appreciate this commenter's feedback. Based on our review of responses received in previous submissions we found responses to be duplicative in questions that referenced safety and/or treatment risk. We revised this ICR such that respondents can discuss safety and/or treatment risks in response to the same questions in an effort to streamline the information requested. We assure this commenter that several questions in this ICR (Questions 46f, 46f1, and 46f2) explicitly request information on treatment risk or safety (Questions 39, 46, 52).

Comment: A couple of commenters suggested that CMS remove the requirement for respondents to provide citations in the *Patient or Caregiver-Focused Input* section. A commenter requested that CMS allow patients, clinicians, and patient organizations to submit a letter or direct entry form without citations or technical requirements. A commenter stated that CMS should not use the CMS HPMS for submissions for the public. A commenter stated that CMS should ensure that the structure and content of Section I accommodate a wide range of quantitative and qualitative inputs from various stakeholders types while maintaining transparency and methodological rigor. One commenter suggested that CMS conduct targeted outreach to increase participation in the ICR and create user-friendly materials and resources to aid in the completion of the submission. A couple of commenters suggested including a glossary with system functionality to view the definitions as a pop-up window

when included in an applicable instruction and/or question. A commenter suggested CMS provide a structured crosswalk through which a manufacturer can identify the dossier pages or sections related to ICR questions to avoid duplicative web-form entry.

Response: Consistent with our response to the ICR for initial price applicability year 2028, we note that the Additional Instructions to Section I indicates that responses that are sharing a personal experience with prescribing or taking the selected drug and/or its potential therapeutic alternative(s) or responses by a respondent that is a caregiver describing the experience of the person taking the selected drug and/or its potential therapeutic alternative(s) do not need to include citations.

We appreciate concerns about the user interface for the CMS HPMS. Consistent with our response to similar comments in the initial price applicability year 2028 version of this ICR, we reiterate that we appreciate and collect feedback shared by interested parties to continue to identify opportunities to improve the user interface for the submission of responses to this ICR. We also note that the CMS HPMS adheres to CMS and HHS policies, procedures, controls, and standards for information security and privacy. Additionally, CMS conducts outreach to patient advocacy organizations, disease groups, and other consumer associations regarding public engagement opportunities, including the section 1194(e)(2) data submission.

Comment: A couple of commenters expressed concern that the ICR does not require respondents to disclose whether their response(s) include quality-adjusted life-years (QALYs) and recommended that CMS require anyone submitting evidence to disclose whether the underlying studies used QALYs, equal value of life years gained (evLYG), or similar measures.

Response: We thank commenters for their input. Consistent with our response to similar comments in the initial price applicability year 2028 version of this ICR, we note that in previous ICRs that included a requirement for respondents to indicate if a QALY or other prohibited measure was included in their response, the response rate was low. We believe this may be because not all respondents to this ICR are familiar with cost-effectiveness measures sufficiently to provide relevant information to fulfill the requirement. We also note that CMS reviews all cost-effectiveness measures used in studies relevant to a selected drug to determine whether the use of the measure is permitted in accordance with section 1194(e)(2) of the Act as described at paragraph (e) of this section, as well as section 1182(e) of the Act and other applicable law per § 429.505(e)(1). Additionally, we reaffirm that per § 429.505(e), we will not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

Comment: A commenter recommended that CMS create a dedicated ICR section for patient organizations to include information on formulary placement, utilization management, and affordability across the patient population they represent.

Response: We appreciate this commenter's suggestion. However, we believe that the questions grouped under "Patient or Caregiver Input" in combination with the opportunity to respond to any question in Section I of this ICR provide ample opportunity for a patient organization to

contribute on behalf of the population they represent. We recognize that patient organizations may have broad perspectives on a patient population, and we encourage such entities to respond to all questions in Section I that may be relevant to their expertise. We also note that Question 47 of Section I inquires about health insurance coverage or access issues related to the selected drug and its therapeutic alternative(s) and that Question 49 provides an opportunity for respondents to share additional information that they believe CMS should consider.

Comment: A commenter suggested the ICR should more clearly prioritize evidence related to therapeutic impact, unmet medical need, patient experience, and improvements in health outcomes.

Response: We appreciate this commenter's input. The ICR is not intended to prioritize evidence but rather to collect evidence related to the factors listed at section 1194(e) of the Act for consideration in developing the initial offer and counteroffers. We refer the commenter to section II.F.3. and § 429.510 of the Negotiation Program final rule for more information on how we consider the information provided in this ICR.

Manufacturer-Focused Input

Comment: A commenter suggested CMS provide a template to standardize the parameters that may be included in manufacturers' responses, such as cost, prevalence, and utilization.

Response: CMS thanks this commenter for their feedback. Consistent with our response to a similar suggestion in the initial price applicability year 2028 version of this ICR, we decline to provide a template for responses to Section I. Per § 429.510(e), we will collectively consider the information provided by the interested parties in response to questions about section 1194(e)(2) factors.

Clinical-Focused Input and Health Research-Focused Input

Comment: A commenter suggested CMS request information from clinicians about observed differences in treatment access including among individuals living in rural areas, people with disabilities, and others who may experience reduced access due to geographic, socioeconomic, or functional factors. The commenter also stated that such responses should address relevant patient-centered outcomes in addition to traditional clinical endpoints.

Response: CMS thanks this commenter for their feedback. We refer the commenter to Question 47 which requests treatment-related information on access and patient information from clinician respondents or others who chose to answer Question 47. Similarly, a respondent may provide any additional information they would like CMS to consider in its evaluation of the selected drug in each of the respondent subsections. Finally, we remind interested parties that any member of the public, including community organizations, clinicians, and other providers, may respond to Section I. We believe these questions provide sufficient opportunity for respondents to contribute information on treatment access and patient-centered outcomes as they see fit.

Question 57: Identification of Information Submitted in Section I that the Respondent Believes Should be Withheld as Proprietary Information

Comment: A commenter requested that CMS publish anonymous, aggregated versions of all responses. A commenter suggested that CMS adopt a narrow approach to proprietary designations such that redactions be narrowly limited to trade secrets or information demonstrably likely to cause competitive harm if disclosed. The commenter stated this would support transparency.

Response: Consistent with our response to a similar comment in the initial price applicability year 2028 version of this ICR, we note that we include redacted copies of all submissions to Section I with the explanation of agreed-upon MFPs. Section II.D.1. of the proposed rule (91 FR 36273) states that a Primary Manufacturer may indicate for CMS which information the Primary Manufacturer believes should be withheld from disclosure by CMS consistent with existing Federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of the FOIA, and that are not included under proposed § 429.300(c) as data that must be deemed proprietary information by CMS. We direct commenters to § 429.300 for more information.

Questions 57 through 59: Other Public Input

Comment: A commenter suggested the "Other Public Input" section should clarify that responses may include information from community-based organizations, health systems, or other civic institutions to provide information on the indirect effects that CMS should consider such as impacts on the caregiving workforce or public health infrastructure as well as information on areas where evidence is lacking, particularly for conditions that are less common or for patient populations with limited access to necessary treatments.

Response: We appreciate the suggestions offered by the commenter. Similar to the response above, we reiterate that Section I of this ICR is open to any interested party and that respondents may answer any questions in this section, including open-ended questions that offer opportunities to discuss the points laid out by this commenter. We will consider the information provided in this ICR in accordance with § 429.510(e).

Questions 60 and 61: Visual Information and Citations

Comment: A couple of commenters requested that CMS remove the limit on submission of visual representations allowed in Question 60 as it is arbitrary and may be restrictive for some respondents. A commenter requested that CMS remove the limit on the number of citations that may be provided in Question 61 for the same reasons. A commenter asked that CMS clarify whether the limitations in Questions 60 and 61 are per drug or per respondent.

Response: We thank these commenters for their feedback. Consistent with our response to similar concerns in the initial price applicability year 2028 version of this ICR, we believe that the number of visual representations permitted in Question 60 and the number of citations permitted in Question 61 (250 citations total) is appropriate to capture the estimated amount of information necessary to provide a sufficient answer to the questions posed in Section I. This

is based on our review of actual responses submitted for Section I in initial price applicability years 2026, 2027, and 2028. We have also observed in past submission years that respondents may rely on the same source across questions, and for these instances, the respondent should only include a citation one time in response to Question 61. We also note that the limitations in Question 60 and 61 are per drug. Further, we believe that the volume and breadth of information identified among public submissions and CMS' review captures adequate evidence about potential therapeutic alternatives for the selected drug.