Center on Health Policy at BROOKINGS

June 26, 2025

Chris Klomp
Deputy Administrator and Director
Centers for Medicare and Medicaid Services

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Dear Deputy Administrator Klomp:

Thank you for the opportunity to comment on CMS's draft guidance on the Medicare Drug Price Negotiation Program. This group of experts writes to provide comments on four main areas of the draft guidance.

Section 30.1: Identification of Qualifying Single Source Drugs (Combination Drugs)

We are encouraged to see CMS specifically requesting comment on the role of combination drugs in the identification of the qualifying single source drug (QSSD). To date, CMS has defined a QSSD for drug products as "all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs" (with an analogous definition for biological products). This definition follows on from Social Security Act (the Act) Section 1192(d)(3)(B)'s aggregation provision, instructing CMS to "use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended-release formulation." This definition also gives effect to Congress' intent to limit incentives for a form of "product hopping," in which manufacturers would reformulate existing products in an effort to distribute sales across products to reduce the likelihood of being selected for negotiation. If a manufacturer could avoid being selected for the negotiation program by developing an extended-release version of the same active moiety, for example, it would, at best, limit the ability of Congress to achieve its intended goals. At the very least, CMS should maintain its current definition of a QSSD.

In the spirit of defining a QSSD to advance Congressional intent, we also think CMS should go further as it relates to combination drugs. In the 2026 and 2027 cycles of the negotiation program, CMS has treated "fixed combination drugs," defined as "with two or more active moieties/active ingredients," as a distinct product from their component parts for purposes of identifying QSSDs for negotiation program eligibility. But this is not clearly required by statute. Relatedly, we note the guidance's current reference to and reliance on FDA's regulation at 21 C.F.R. § 300.50 defining a "fixed-combination prescription drug" and stating that "two or more drugs may be combined in a single dosage form when each component makes a contribution to the claimed effects," where a "special case" of this rule is when "a component is added to enhance the safety or effectiveness of the principal active component."

CMS should not necessarily follow this regulation, which was first finalized in 1971[1] and serves a very different purpose than does the negotiation program. The role of a combination drug designation is to determine the type and quantity of evidence required for product approval.[2] CMS, by contrast, is aiming to interpret the IRA's statutory instructions to identify a QSSD by aggregating data in a particular way. In our view, CMS is right to conclude that different types of combination drugs ought to be treated differently for purposes of QSSD aggregation. Some combination drugs should be considered as a "new formulation" of the original active moiety, for aggregation purposes, while others should be considered as their own combination for QSSD purposes.

We do not think CMS must determine conclusively in the final guidance the circumstance of every possible type of combination drug. But we do think it is reasonable for CMS to determine that "fixed combination drugs for which one of the active ingredients or active moieties contained is not biologically active against the disease state(s) the drug is indicated for and thus does not result in a clinically meaningful difference" should be aggregated with the relevant active ingredient or moiety for QSSD purposes, and to apply its judgment regarding which products fall within this category. CMS can reserve additional classes of combination drugs for later analysis, as it may become necessary. Support for this distinction could be drawn from the "special case" in the FDA regulation referred to by CMS, because FDA itself differentiates between the typical fixed combination drug case and the case when "a component is added to enhance the safety or effectiveness of the principal active component."

In the case in which one of the active ingredients or active moieties is not biologically active against the relevant disease state, such a reformulation with that active ingredient or active moiety is more akin to an alternative mode of delivery, even though FDA may refer to the compound in question as an active ingredient or active moiety. In this case, where the active moiety or ingredient primarily affects the bioavailability or absorption of the other active moiety or active ingredient, this would imply including the combination drug with the products that share the other active ingredient or active moiety. Failure to do so opens the door to adding a benign active ingredient to a product for the purposes of creating a new drug for negotiation considerations, undermining CMS's ability to implement the negotiation program.

Section 50.1: Forward-Looking Market Data

It is reasonable for CMS to solicit forward-looking market data, as such data can potentially affect the negotiating stance taken by the agency. However, because under Section 1194(e) of the Act, "market data" can only be submitted by the manufacturer and not by the public, we urge caution in both collecting and interpreting such data. As one example, a manufacturer might cite a particular date of expected patent/exclusivity expiration and generic or biosimilar entry as a reason for CMS to make a higher offer. But it is also in the manufacturer's interest to work to delay such generic or biosimilar entry, and notable cases (such as involving Humira, in which the first

[1] Food & Drug Admin., *Fixed-Combination Prescription Drugs for Humans*, 36 Fed. Reg. 20037 (Oct. 15, 1971).
[2] In Re Alcon Lab's Inc., 13 U.S.P.Q.2d 1115 (Com'r Pat. & Trademarks 1989) (quoting from a May 10, 1989, letter from Stuart Nightingale, M.D., Associate Commissioner for Health Affairs at FDA).

biosimilars did not enter until six years after AbbVie initially expected)[3] provide reason for concern.

CMS might mitigate these concerns in part by asking the manufacturer to submit additional sources of forward-looking information, such as 10K and 10Q SEC filings, that contain future-looking assessments of opportunities and risks. These filings are subject to considerable scrutiny by investors and analysts. While there is a safe harbor for projections, the provision of misleading information is the subject of lawsuits. The SEC has repeatedly considered the value of such "soft" information and has found it worthwhile to include in filings.

Importantly, future projections are typically, by definition, uncertain and, as a result, rely on subjective factors. CMS might consider relying only on market data supported by actual occurrences. For example, the 2028 draft guidance provides the example of "a substantial WAC price decrease planned for a selected drug to be implemented prior to the first initial price applicability year for the selected drug." If that WAC price decrease had already occurred prior to the onset of the negotiation period but had occurred after the data were gathered on which the selection of the drug was based, CMS might more confidently rely on it.

Sections 60.3.3 and 60.3.4: Factor Adjustment

CMS has solicited comments on whether the agency should place "greater emphasis" on certain Section 1194(e)(1) or 1194(e)(2) factors in determining the preliminary price or adjusting that price. In past cycles of the negotiation program, CMS has received comments that would encourage the agency to adopt a formulaic approach to the negotiation process, and we encourage the agency to maintain its existing approach. As CMS noted in the revised guidance for initial price applicability year 2026, "CMS believes it is important to maintain flexibility when considering how each negotiation factor contributes to the initial offer and final offer, if applicable, which may be impacted by the unique characteristics of each selected drug, the populations each selected drug is intended to treat, and information that may emerge from meaningful discussions with manufacturers, patients, and patient representatives."[4]

The qualitative approach outlined by CMS as part of the 2026 and 2027 cycles of the program is sensible, given the great diversity of circumstances across products subject to negotiation. While many of the Section 1194(e)(1) factors rely on extensive quantitative assessments, consideration on how in the aggregate they might be considered alongside each other may, in part, interact with Section 1194(e)(2) factors. The emphasis CMS places on various factors will, therefore, vary

[3] U.S. House of Representatives Committee on Oversight and Reform, Drug Pricing Investigation: AbbVie—Humira and Imbruvica, at 22 (May 2021), https://docs.house.gov/meetings/GO/GO00/20210518/112631/HHRG-117-GO00-20210518-SD007.pdf.

[4] Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 57 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf; *see also* Ctrs. for Medicare & Medicaid Servs., Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, at 99 (Oct. 2, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

according to the therapeutic context for the drug, the nature of the disease(s) that the product is used to treat, the populations served, and the financial history of the product, among other details. Negotiation on behalf of the U.S. public must rely on CMS's ability to flexibly take account of the full set of considerations outlined in the statute in developing price offers and the agency's negotiation stance.

We also underscore that this approach is the proper application of Social Security Act Section 1194(b)(1), which directs the agency to develop a "consistent methodology and process" that "aims to achieve the lowest maximum fair price for each selected drug." An overly formulaic process for negotiation would fail to give meaning to the statutory instruction by limiting the agency's ability to achieve the lowest negotiated price. Nor would it be consistent with the instruction in Section 1194(e), which directs the agency to "consider" a wide variety of factors, some of which are by their nature qualitative and therefore could not be given the statutorily mandated "consider[ation]" if the agency were to eliminate the flexibility of its current policy.

Section 130: Renegotiation

In previous work, two of us (R.S. and R.G.F.) have written a white paper[5] (attached to this comment, for reference) articulating policy options for CMS regarding the implementation of Section 1194(f)'s renegotiation provisions. We are encouraged to see so many similarities between our suggestions and the discussion in Section 130 of the draft guidance regarding the implementation of the renegotiation process. For example, we are encouraged to see CMS thinking expansively about the types of evidence that might matter in determining whether there has been a "material change" in a Section 1194(e) factor for purposes of identifying renegotiation-eligible drugs. We have two suggestions for the agency at this time.

First, in determining whether renegotiation is likely to result in a significant change in the MFP, it appears that CMS is proposing to consider both "the likelihood that the new indication or material change would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP" and "whether such a change in the MFP for the renegotiation-eligible drug would have a significant impact on the Medicare Program." Although CMS is proposing to *consider* both criteria, we would encourage CMS to clarify that a product *meeting* either one of these criteria, but not necessarily both, could still be selected for renegotiation. Consider, in particular, a situation involving the likelihood of a smaller than 15 percent change relative to the current MFP that significantly impacted the Medicare Program. It is easy to imagine, for example, how a 10 percent change relative to the current MFP for a drug that is taken by a large number of Medicare beneficiaries could significantly impact the Medicare program.

Second, we do have concern over the nature of the data collection mechanism envisioned in the draft guidance. That is, CMS recognizes that data collection may be needed to inform renegotiation eligibility for selected drugs and for selection of such drugs. As such, where relevant, CMS proposes to "collect a subset of new section 1194(e)(1) data as a voluntary submission from

[5] Rachel Sachs & Richard G. Frank, *Articulating Policy Options Regarding Implementation of the Medicare Drug Price Negotiation Program's Renegotiation Provision* (Jan. 29, 2025), https://www.brookings.edu/articles/articulating-policy-options-regarding-implementation-of-the-medicare-drug-price-negotiation-programs-renegotiation-provision/.

Primary Manufacturers of selected drugs that do not have a change to long-monopoly status," and Manufacturers may "also voluntarily provide new information about section 1194(e)(2) data for CMS' consideration for purposes of renegotiation eligibility and selection."

We are concerned that 1) making these data collection opportunities voluntary and 2) limiting them to manufacturers (excluding other stakeholders) may bias the data collection efforts in a way that is likely to benefit the manufacturers (rather than the public) and deprive CMS of the most accurate and complete data that can be productively used to identify renegotiation-eligible drugs and select products for renegotiation. In our view, data collection should be mandatory for manufacturers, and additional stakeholders should have the opportunity to submit data as well.

First, by making these data collection opportunities voluntary, manufacturers may choose to disclose only information that would tend to result in an increase in the MFP (for example, if their unit costs of production increased, or if new comparative clinical effectiveness data is available that is favorable for their product) and would be less likely to disclose information that would tend to result in a decrease in the MFP (for example, if their unit costs of production decreased, or if new comparative clinical effectiveness data is available that is unfavorable for their product). Making data collection mandatory minimizes these concerns.

Second, another option to respond to this potential concern is to also provide a voluntary data collection opportunity from the public. Other stakeholders may, for example, identify new comparative clinical effectiveness data that might be less favorable to the Primary Manufacturer and would be interested in submitting it to CMS. However, this option would only be useful as it relates to the Section 1194(e)(2) factors. If CMS believed that it would be useful to gather additional information regarding the Section 1194(e)(1) factors, CMS must make this data collection opportunity mandatory for manufacturers. CMS could frame the relevant questions so as to avoid additional data collection burdens on the agency staff. For example, for several of the Section 1194(e)(1) factors, CMS could ask manufacturers only about changes in the information previously submitted, rather than soliciting all of the information anew.

Conclusion

We thank CMS for the opportunity to provide comment on this draft guidance and are available to discuss these issues at any time.

Sincerely,

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1. Rachel Sachs & Richard G. Frank, *Articulating Policy Options Regarding Implementation of the Medicare Drug Price Negotiation Program's Renegotiation Provision* (Jan. 29, 2025), https://www.brookings.edu/articles/articulating-policy-options-regarding-implementation-of-the-medicare-drug-price-negotiation-programs-renegotiation-provision/.

BROOKINGS

COMMENTARY

Articulating policy options regarding implementation of the Medicare drug price negotiation program's renegotiation provision

Rachel Sachs and Richard G. Frank

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The Inflation Reduction Act (IRA) of 2022 included a number of provisions to reform how the federal Medicare program pays for prescription drugs (encompassing both small molecule drugs and biological products) for its beneficiaries. One key provision of the IRA was the creation of a Medicare drug price negotiation program, allowing Medicare to negotiate a "maximum fair price" (MFP) directly with drug manufacturers for a limited number of qualifying single-source drugs each year. The IRA calls for the first set of negotiated prices to take effect in 2026, and the Centers for Medicare and Medicaid Services (CMS) recently completed the negotiation process for the first set of drugs and published its explanations for each of the negotiated MFPs. Earlier this month, CMS announced the second set of drugs selected for the negotiation program, with any negotiated prices taking effect in 2027.

However, the IRA also specifies that other provisions of the negotiation program will not take effect until future years of the program. In particular, the statute articulates a process of *renegotiation* beginning in the 2028 cycle of the program. That means that CMS would seek to renegotiate an MFP for drugs that it had previously selected for the negotiation program and agreed to an MFP in a prior cycle of negotiation. CMS has yet to promulgate guidance for the 2028 cycle of the program and make its views public regarding the structure of the renegotiation process. In this piece, we identify three key questions CMS will face in implementing and operationalizing the

renegotiation process for the program and offer policy options for the agency to consider.

What counts as a “renegotiation-eligible drug”?

As articulated under section 1194(f) of the Social Security Act (42 U.S.C. 1320f-3(f)), the “renegotiation process” applies only to “renegotiation-eligible drug[s].” The statutory definition of “renegotiation-eligible drug” provides three ways in which a selected drug may become eligible for renegotiation.

First, a selected drug “for which a new indication is added” is eligible for renegotiation. Here, CMS must determine under what circumstances a new indication has been added for a drug. CMS’ guidance ↗ for the 2027 cycle of the negotiation program distinguishes between an “indication” for a selected drug and the term “FDA-approved indication,” allowing the agency to consider situations in which the drug is used for conditions for which it is not currently FDA-approved (off-label use). For consistency, CMS would likely apply this interpretation of the term “indication” in the renegotiation context as well. That is, a drug which received FDA approval for a new indication would be included within this category, but potentially also a drug for which a new indication has been added “in nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia,” as stated in the current guidance.[1]

Second, a selected drug that experiences a “change in status” to become either a long-monopoly drug or extended-monopoly drug qualifies as “renegotiation-eligible.” These terms—long-monopoly and extended-monopoly—are defined elsewhere in the statute as they relate to the amount of time since a drug was first approved by FDA and are currently fairly mechanical in their application. An extended-monopoly drug has been first approved for at least 12 years and less than 16 years with respect to the initial price applicability year, while a long-monopoly drug has been first approved for at least 16 years.

Third and most notably, the statute (at section 1194(f)(2)(D)) includes as a renegotiation-eligible drug “a selected drug for which the Secretary determines there has been a material change of any of the factors described in paragraphs (1) or (2) of subsection (e)” (emphasis added). Procedurally, this language specifically commits

the question of whether there has been a "material change" to the determination of the Secretary. It is also substantively limited, though, to considering sections 1194(e)(1) and (e)(2).

In general, the 1194(e) factors are those that Congress has specified CMS "shall consider" "as the basis for determining the offers and counteroffers" under the program. Each of these factors has been given operational effect in existing guidance documents and information collection requests from CMS.[2]

The section 1194(e)(1) factors, or "manufacturer-specific data," include the "research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs," the "current unit costs of production and distribution of the drug," the "prior Federal financial support for novel therapeutic discovery and development with respect to the drug," "data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 355(c) of title 21 or section 262(a) of this title for the drug," and "market data and revenue and sales volume data for the drug in the United States." Section 1194(e)(1) specifies that these data must be "submitted by the manufacturer."

The section 1194(e)(2) factors, or "evidence about alternative treatments," include "the extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives," "prescribing information approved by the Food and Drug Administration for such drug and therapeutic alternatives to such drug," "comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations," and "the extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy." Unlike with section 1194(e)(1), section 1194(e)(2) does not require this information to be submitted by the manufacturer and merely instructs CMS to consider such evidence "as available." Currently, CMS' procedures include consideration of evidence relevant to these factors that are submitted by members of the public (as well as manufacturers).

Given these factors, what should CMS consider to be a "material change"? Non-exhaustively, in our view, CMS should consider at least the following factors to be relevant to the question of whether there is a "material change."

- Section 1194(e)(1)(A): Assuming the manufacturer has not recouped its R&D costs at the time of its initial negotiation, recoupment of R&D costs should qualify as a "material change."
- Section 1194(e)(1)(B): A significant increase or decrease in the manufacturer's unit costs of production and distribution should qualify as a "material change."
- Section 1194(e)(1)(D): If primary patents or FDA-granted exclusivity periods expire or are invalidated and competition has not yet emerged in the form of an approved small-molecule generic or biosimilar, it should qualify as a "material change."
- Section 1194(e)(2)(A): It should qualify as a "material change" if other drugs are approved or existing drugs have new indications approved that render the selected drug no longer a therapeutic advance as compared to existing therapeutic alternatives; alternatively, it should qualify as a "material change" if the costs of those existing therapeutic alternatives change—for example, if a generic or biosimilar is approved and marketed for a therapeutic alternative, or if an existing therapeutic alternative is selected for negotiation and negotiates an MFP that is lower than its previous price.
- Section 1194(e)(2)(B): It should qualify as a "material change" if the prescribing information for the drug changes meaningfully, such as if an accelerated approval indication is withdrawn or a safety warning, such as a newly identified side effect or contraindication, is added.
- Section 1194(e)(2)(C): It should qualify as a "material change" if additional evidence regarding comparative effectiveness becomes available, particularly one that adds significantly to the existing body of comparative effectiveness evidence. For example, if a new head-to-head study is released regarding the selected drug's efficacy relative to its most prominent therapeutic alternative.
- Section 1194(e)(2)(D): It should qualify as a "material change" if a selected drug no longer meets an unmet medical need, which may depend on whether other therapeutic alternatives become available for the conditions at issue.

A significant procedural question underlies these issues. Specifically, what procedures should CMS put in place to allow the agency to determine whether one of the above circumstances has changed? Some questions about changes in circumstances may be answerable based on publicly available information, such as if there is a withdrawal of an FDA-approved indication under section 1194(e)(2)(B). CMS would also be aware, for example, if an existing therapeutic alternative is selected for negotiation and negotiates an MFP that is lower than its previous price under 1194(e)(2)(A) (as CMS is doing the negotiation). In general, though, CMS should consider setting up alternative processes to receive relevant information. One option would be for CMS to require manufacturers of selected drugs to re-submit information about the section 1194(e)(1) factors, as relevant, to determine whether such a "material change" has occurred. Another possibility would be for CMS to maintain an open process for receiving information from the public regarding the 1194(e)(2) factors. In other circumstances, CMS can monitor on its own for these types of developments (such as in the 1194(e)(2)(B) example) and should consider whether additional data sources may be available for use in this area.

Which renegotiation-eligible drugs should be selected for renegotiation?

Section 1194(f)(3) instructs CMS to "select among renegotiation-eligible drugs for renegotiation" as the statute specifies. CMS is directed to select "all" renegotiation-eligible drugs which experience a "change in status" to a long-monopoly drug or extended-monopoly drug, as noted above. But among drugs that qualify as "renegotiation-eligible drugs" due to the addition of a new indication or where there has been a "material change," CMS is directed to select eligible drugs "for which the Secretary expects renegotiation is likely to result in a significant change in the maximum fair price otherwise negotiated" (emphasis added). Procedurally, as with the question of which drugs qualify as eligible for renegotiation, this language is important because it specifically poses the question of when it is "expected" that renegotiation "is likely to result in a significant change" in the MFP to the Secretary.

Under what circumstances should CMS "expect" that renegotiation "is likely to result in a significant change" in the MFP? CMS may wish to establish presumptions regarding when a "material change" would be "likely to result in a significant change" to the MFP without prejudging the results of the renegotiation process. Answers to this

question are likely to be context-dependent and driven by CMS' views of the negotiation process in the first instance. That is, CMS has information about which of the factors in 1194(e) "drove" its determination of the initial offer and resulting agreed upon MFP. In making this determination, it might be the case that the evidence about alternative treatments (the section 1194(e (2) factors) will assume greater importance than the manufacturer-specific data (the section 1194(e)(1) factors) because CMS has stated that its analysis begins with the evidence about alternative treatments in formulating a preliminary price for the initial offer, and then adjusts for the manufacturer-specific data.

As a result, CMS might state that material changes to any of the section 1194(e)(2) factors—such as the approval of a new therapeutic alternative, the introduction of generic or biosimilar competition for a therapeutic alternative, or significant changes in utilization in a certain condition—are likely to be of particular importance here. These types of factors are frequently economically meaningful determinants in the market pricing of a particular drug. To the extent that these types of events would be likely to significantly change the price negotiated in other markets, these types of events should be considered similarly likely to significantly change the negotiated MFP.

As one example, a newly marketed generic or biosimilar version of a therapeutic alternative should reduce the relevant price of that alternative and might, therefore, influence CMS' initial renegotiation offer. In CMS' view, though, whether this is likely to be the case may depend on the utilization of both therapeutic alternatives relative to the selected drug and also the utilization across indications of the selected drug. Focusing on utilization across indications, consider a selected drug with two indications, one which accounts for 90% of the drug's prescriptions and one which accounts for just 10%. The introduction of a generic competitor for a therapeutic alternative for the indication comprising 90% of the drug's utilization may be thought to be more important to CMS' analysis than the introduction of a generic competitor for a therapeutic alternative for the indication comprising just 10%, particularly if the therapeutic alternative for the 90% indication has significant market share as against the selected drug. It is possible, though perhaps less likely, that certain changes to the section 1194(e)(1) factors might have a similar effect.

These same types of considerations would likely be relevant to the question of when CMS would "expect" that the addition of a new indication "is likely to result in a

significant change" in the MFP. A new indication that shifts market share for a particular drug or that impacts competition within a class would be more economically meaningful than new indications that had limited impact on prescribing patterns for the selected or other drug.

What procedures might CMS propose for the renegotiation process?

Section 1194(f)(4) states that CMS "shall specify the process for renegotiation of maximum fair prices with the manufacturer of a renegotiation-eligible drug selected for renegotiation under this subsection" and specifies that the "process (...) shall, to the extent practicable, be consistent with the methodology and process" under the standard negotiation program. CMS should carefully consider its acquisition and use of data as part of this process.

For example, imagine a situation in which a therapeutic alternative for a selected drug newly has generic competition, such that CMS would "determine" that there has been a "material change" to section 1194(e)(2)(A). Further, imagine that the price of this therapeutic alternative was a key analytical piece in forming the initial offer, such that if this therapeutic alternative had a much lower price due to generic entry, CMS "expects renegotiation is likely to result in a significant change" in the MFP. In such a case, CMS ought to consider what information the manufacturer and public have or should have as part of this process. For example, CMS has now published its explanation for each negotiated MFP, and both the manufacturer and the public now have information about what CMS considered to be therapeutic alternatives for the selected drug, and the fact of generic entry would be public. The net price of the generic (and of its reference branded therapeutic alternative) would not be known to the manufacturer of the selected drug, however, it is likely to be known to CMS. To carry out the renegotiation program, what information does the manufacturer and the public need to have, and at what point? What information does CMS need to have, and when? When CMS informs a manufacturer that its drug has been selected for renegotiation, for example, CMS needs to have done so on the basis of information—but must it disclose that information to the manufacturer or specify on what basis the manufacturer was selected? By contrast, all information about whether a selected drug has experienced a change in status to become either a long-monopoly drug or

extended-monopoly drug is likely to be public, such that demonstrating eligibility under 1194(f)(2)(B) or (C) may be easier.

In answering these questions, CMS should consider how it can best use the information it has made available publicly as part of its explanation of the negotiated MFPs, which the IRA instructs it to provide. As part of its public explanation of each negotiated MFP, CMS has now made available publicly the indications, list of therapeutic alternatives for each indication, and list of safety and effectiveness outcomes for each selected drug for the 2026 cycle, in addition to other information CMS used as part of the negotiation process. If CMS decides that a "material change" has occurred if a generic or biosimilar enters for a therapeutic alternative and that it expects a "significant change" in the MFP as a result, CMS should communicate that information to the manufacturer in explaining its selection of the drug for renegotiation. CMS would not, however, need to communicate the relevant net prices of the generic or its reference branded therapeutic alternative to the manufacturer, nor would it typically be able to communicate such proprietary net price information. The fact of generic entry and the typical market impact of such generic entry on price would be sufficient to justify CMS' selection of the drug for renegotiation.

Although the statute does not seemingly require CMS to offer a public explanation here—in other cases, the statute requires a public explanation, as with the explanation of the MFP, but here it seemingly does not—CMS should strongly consider communicating as much of this information as it can publicly as well. CMS could provide the reason for selection, referencing the fact of generic entry, approval of a new therapeutic alternative, or other changes in the relevant comparative effectiveness landscape as relevant. The types of presumptions we articulate above may be more important for CMS as it defines its procedures regarding both the renegotiation program and the disclosure of information publicly.

As CMS prepares to implement the additions made by Congress for the 2028 cycle of the Medicare drug price negotiation program, the operationalization of the IRA's renegotiation program will be a key topic for the agency. Fortunately, CMS has already made important legal and policy decisions in operationalizing the program for the 2026 and 2027 cycles. Our analysis here builds off of CMS' existing framework and provides policy options for the agency to consider.

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Footnotes

1. See Section 50.2 p.241 footnote 121 of the guidance memo entitled: Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 of October 2, 2024.

2. See, for example, Appendix A of the guidance memo entitled Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 of October 2, 2024; see also

the Negotiation Data Elements ICR Form (https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202411-0938-010&icID=272617 ↗).