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RE: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

Dear Dr. Seshamani,

Thank you for inviting comments on the Initial Memorandum on Implementation of Sections 11001 and 11002 of the Inflation Reduction Act. We are pleased to offer the comments set out in what follows. We hope you find them useful in your efforts to implement this important legislation. Our comments are organized to correspond to the outline of the guidance.

Section 30: **Identification of Selected Drugs**

30. *Definition of a drug for negotiation* Purposes: The Guidance defines a drug as encompassing all products associated with an API. This is a sensible choice. The price of a drug should include all the generic versions in the price estimate. Including the generic version product(s) captures all the volume associated with an API. Failure to do so would overweight brand-name formulations in calculation of the price of a drug.

30.1: CMS should establish a standard that defines the minimum share of the drug at the API level that is subject to generic or biosimilar competition. In small molecule markets with high levels of total spending (over $500 million) the average generic penetration one year post generic entry is about 65%. Thus, establishing a trigger at 50% to 65% would be based on recent history reflecting the experience of drugs facing true competition from generics.[1] For biosimilar products the initial market shares are considerably lower. Although the evidence is more limited, market shares for biosimilars have been on the order of 20% to 25% a year after entry.[2] The implication is that if the generic or biosimilar shares of the API fall below the trigger values, the API remains in an uncompetitive market and should remain subject to negotiation.

To estimate generic or biosimilar market share at the API level, a standardized volume measure would need to be applied across dosage forms and strengths. Options include the number of claims (for Part B), standardized prescriptions (for Part D) or defined daily doses. For example, one could

[1] See appendix at the end of the comment for examples of studies offering evidence on this.
[2] See appendix at the end of the comment.

use Part D claims data to estimate whether more than 50 percent of standardized prescriptions among all the API formulations were dispensed for a generic drug.[3]

30.1.2 It is not clear if rebates will be incorporated into determining whether a drug has spending below $200,000,000. Rebates should be included because some drugs have rebates of 80-90% and not including the rebates would yield choices of products that would not reflect true spending by taxpayers.

30.2 *Integration of Rebates Assessment of Spending Exemptions*: It is not clear if rebates will be incorporated into calculations used in the ranking of the 50 negotiation eligible drugs. Footnote 30 attached to point 30 of the guidance suggests that the proposal is to not account for rebates. This works for the selection of the initial 50 negotiation eligible drugs because it makes the data and the selection process transparent. To use rebates in the calculation would disclose rebate data which needs to remain confidential. One possible solution may be that after CMS identifies the top 50 drugs, CMS should exclude any drugs that already have rebates that put their current net price at or close to what would be the maximum fair price ceiling. The statute might provide some flexibility on which one they choose among those that are otherwise eligible.

30.3.1.2 The metrics proposed to assess operational readiness are generally sensible. However, SEC filings about future revenues are nearly always subject to significant caveats around uncertainty and changing market conditions. CMS should consider a more concrete indicator of readiness.

30.3.1.1(3) There is guidance addressing whether there is "bona fide marketing" of the competitor. That review is an important part of the proposal for assessing the legitimacy of potential exclusion of drugs. It could be crafted broadly enough to encompass the type of limited use of a biosimilar as well. It will be necessary to define a "bona fide" competitor. See comment on 30.1 for more information on how to define a "bona fide" competitor.

Section 40: Requirements for Manufacturers of Selected Drugs

40.2 The decision to require the manufacturer to submit data on new and approved NDC-11s or discontinued NDC-11 is appropriate. The provision should ask for the most recent sales for any discontinued NDC-11s.

40.2.2 *Disclosure of Data Used in negotiations and its destruction*: It is not clear what the implications are of an individual engaged in the process disclosing the information to others. The penalties for companies are clear but not for the individuals engaged in the process. People with negotiation information leave companies and the government all the time.

40.2.3 If sales data for specific drugs are available from IQVIA and other claims data sources, why should the volume of sales be treated as confidential? Making it public would allow for independent assessment of the accuracy of reporting.

[3] Both CBO and MedPac have standardized prescription sizes in Part D to 30 days' supply in their published reports.

40.3 *Agreements on negotiation and renegotiation*: It is not clear the specific conditions under which a renegotiation will occur in subsequent years.

40.4 The negotiated drug should get favorable placement by the PBM/PDP. This will lower Medicare and Medicare beneficiary spending and give the drugs in the same therapeutic class the incentive to lower their prices. Medicare should prohibit spread pricing for these drugs.

Section 50: Negotiation Factors

50.1 The reporting of whether a pharmaceutical manufacturer recouped its costs should be subject to comparison with a CMS analysis of the individual components of data items related to R&D costs reported by the manufacturer and in SEC filings. This is because the assessment of whether costs were recouped is subject to a variety of arbitrary allocation and discounting assumptions that may not be applied by manufacturers in a fashion that is consistent with the public interest or best practices.

50.1 In considering prior federal financial support CMS might consider tax credits provided through the Orphan Drug program and similar subsidies in addition to grants and contracts that seem to be implied by this section.

50.2 Other countries conduct and compile comparative effectiveness studies. The negotiation process would benefit from review of the and the findings of these comparative effectiveness studies and the methods used by these countries. CMS should also examine the prices in these countries. The guidance should clarify whether studies conducted in other countries can be used in comparative effectiveness assessments.

50.2 CMS should specify how the comparative effectiveness of two drugs would be considered If one drug is a cure and another drug requires ongoing treatment. For example, the price of a drug that is used to treat a chronic condition (arthritis) that is used continuously over years should be treated differently than the price of a drug that is used for a short period of time and then never again because a cure has been achieved (Hepatitis C drugs). The comparative effectiveness measure should examine the lifetime cost and effectiveness of both treatments.

50.2 The guidance notes that CMS will use FDA approved prescribing information in the negotiation process. The information that is contained on the product labels should guide CMS in defining a drug's use.

50.2 There are well-developed alternatives to QALYs that are not subject to concerns about disadvantaging older adults or disabled people, including "equal value life year gained" (evLYG). They have been employed in numerous settings for reasons precisely consistent with Congressional intent. In addition, metrics such as the Health Years in Total (HYT) and the Global Risk Adjusted QALY (GRA-QALY) address potential discriminatory features of QALYs and in some cases create a unique advantage for people with disabilities.

Section 60: Negotiation Process

60.1 *Establishment of a single price*: Some drugs are taken for a certain number of months while others are taken the full year. How will this be translated into 30-day equivalents. For example, if a drug needs to be taken for only four months during the year, how will that be translated into 30-day equivalents? In such cases, annual spending levels are appropriate.

60.1 The use of a single price is sensible and consistent with the definition of a drug set forth in Section 30.

60.1 In discussing the determination of a single price, the Guidance uses the term cost (second paragraph under 60.1). That is imprecise because the data being referred to may be either payments or prices and not costs.

60.3 **Therapeutic class**

a. Some brand name drugs are the only option to treat a disease, while others have one or more brand name alternatives available. The PDPs have more negotiating power when there is one or more different brand name drugs that can address the same condition.
b. The challenge is to define the therapeutic categories that define the competing brand name drugs. One commonly used product was developed by US Pharmacopeia, but there are others including the Veterans Affairs (VA) classification code, Medi-Span Generic Product Identifier (GPI), or the IQVIA Uniform System of Classification (USC) that has been used by the Centers for Disease Control and Prevention (CDC).
c. Each of these efforts define a therapeutic category somewhat differently and these differences result in different combinations of drugs in the therapeutic category. Some of the factors explaining the differences include therapeutic category, pharmacology (mechanism of action), chemical structure, and indication.
d. The Guidance should recognize that differing approaches across products are likely to best serve balancing market and clinical issues and having all the different ways to measure therapeutic alternatives available. CMS would be well served to commission a study of the different ways to measure therapeutic class and the strengths and weaknesses of the different existing products. This will help CMS respond to the statements by the drug companies that a drug has brand name competitors according to some measure.
e. It is therefore likely that the best approach to analysis will be drug specific.

60.3 The Part D net price for the alternative therapeutic drugs should include the rebates. Additional data should be collected on the alternative therapeutic drug in addition to price. So that the true market context for establishing transaction prices is considered by CMS in its negotiating position.

60.3.2 It should be made clear that generic drugs will be included in the drugs that are considered therapeutic alternatives in making the initial price offer by CMS.

60.3.2 In adjusting starting prices using comparative effectiveness analysis, it is important to consider how the differences in effectiveness among alternatives would translate into price differentials. This will need to be done on a drug-by-drug basis depending on the circumstances of the negotiated drug and the other drugs in the therapeutic class.

60.3.3.1 The discussion of the effectiveness of therapeutic alternatives proposes to use health outcomes, patient experience, etc. This is appropriate. The Guidance should distinguish clearly how these differ from QALYs (see 50.2 above).

60.4.4 The process set out in this section is appropriate. The evidence on negotiation processes from collective bargaining and other structured negotiations shows that key ingredients are 1) holding informal meeting to discuss issues and identify key pressure points; 2) regular communication; and 3) transparency with respect to how each side is using information. The process outlined in this section might benefit from allowance for additional, less formal meetings or some other channel for communication. Also, establishing some further guidance in the future on how data will be used may further promote reaching agreements in the negotiations. This can be specified after the first round of negotiations.

An issue not discussed in the Guidance – it is unclear if indication-based pricing will be permitted. Indication pricing should be taken into account, but those prices should be combined into the one composite price.

Thank you for your attention to these comments.

Sincerely,

Gerard Anderson and Richard G. Frank

Appendix

1. Examples of studies offering evidence on this point include the following:

   S. Dong-Churl, W.G. Manning Jr., S. Schondelmeyer, and R.S. Hadsall, "Effect of Multiple-Source Entry on Price Competition After Patent Expiration in the Pharmaceutical Industry," *Health Services Research,* 35(2), June 2000, pp. 529-547;

   Congressional Budget Office, *op. cit.*, pp. 28-29;

   H. Grabowski and J. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act," *Journal of Law and Economics,* 35(2), October 1992, pp. 331-350;

   R.G. Frank and D.S. Salkever, "Generic Entry and the Pricing of Pharmaceuticals," *Journal of Economics & Management Strategy,* 6(1), Spring 1997, pp. 75-90;

   Caves, *et al.*, *op. cit.*;

   D. Reiffen, and M.R. Ward, "Generic Drug Industry Dynamics," *The Review of Economics and Statistics,* 87(1), February 2005, pp. 37-49;

   A. Saha, H. Grabowski, H. Birnbaum, P. Greenberg, and O. Bizan, "Generic Competition in the US Pharmaceutical Industry," *International Journal of the Economics of Business,* 13(1), February 2006, pp. 15-38;

   H.G. Grabowski, *et al*., "Updated Trends in US Brand-Name and Generic Drug Competition," *Journal of Medical Economics*, 19(9), April 2016, pp. 836-844;

   R.G. Frank and R.S. Hartman, "The Nature of Pharmaceutical Competition: Implications for Antitrust Analysis," *International Journal of the Economics of Business*, 22(2), 2015, pp. 301-343;

   R.G. Frank, T.G. McGuire, and I. Nason, The Evolution of Supply and Demand in Markets for Generic Drugs, *Milbank Quarterly* 99(3):828-852 September published on-line *June 1,* 2021

2. Ariel Dora Stern et al., Biosimilars And Follow-On Products In The United States: Adoption, Prices, And Users Health Affairs June 2021;

   Frank RG, M Shahzad, WB Feldman, AS Kesselheim, Biosimilar Competition: Early Learning, *Health Economics* 12 January 2022 https://doi.org/10.1002/hec.4471;

   Biosimilars in the United States 2023-2027 - IQVIA