NOSORH

National Organization of
State Offices of Rural Health

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NOSORH Comments on CMS Remedy for the 340 B Acquired Drug Payment Policy - Notice of Proposed Rulemaking (NPRM)

Introduction

On July 11, 2023, the Center for Medicare and Medicaid Services (CMS) of the Department of Health and Human Services published a Notice of Proposed Rulemaking (NPRM) related to a *Remedy for the 340 B Acquired Drug Payment Policy for Calendar Years 2018–2022*. This NPRM proposes an approach to providing remedial payments to affected 340 B Drug Program providers to compensate them for underpayments during years 2018-2022.

In this communication, the National Organization of State Offices of Rural Health (NOSORH) provides its input in response to the NPRM. NOSORH's comments highlight the important role of the 340 B Drug Discount Program in helping to sustain the nation's rural health services system. The comments provide perspective on how the remedial payments can best be managed to best support that system.

NOSORH was established in 1995 to assist State Offices of Rural Health (SORHs) in their efforts to improve access to, and the quality of, health care for over 60 million rural Americans. All 50 states have a SORH, and each SORH helps their state's rural communities to build effective health care delivery systems. NOSORH and its members work closely with rural healthcare providers nationwide, including Rural Health Clinics, Federally Qualified Health Centers, and rural hospitals. NOSORH brings its knowledge of rural essential community providers to the concerns of this RFI.

NOSORH is encouraged by CMS efforts to resolve this longstanding issue but is disappointed that it took several years of litigation to get to this point. NOSORH submitted comments on several occasions dating back to 2018 highlighting what it found problematic with the CMS payment reductions under the 340 B Drug Program. Had those comments been reflected in CMS policy, subsequent litigation and the need for a Court-directed resolution may have been avoided.

NOSORH notes that in the introduction to the NPRM CMS makes the following statement on its intent in making the program payment reduction in 2018:

> "Our intent in implementing this payment reduction was to reflect more accurately the actual costs incurred by participating hospitals in acquiring 340 B drugs. We stated our belief that ***such changes would allow Medicare beneficiaries and the Medicare program to pay a more appropriate amount when hospitals participating in the 340***

B Program furnished drugs to Medicare beneficiaries that were purchased under the 340 B Program (82 FR 59353 through 59371).

NOSORH finds this statement of intent to be at odds with the long-defined purpose of the 340 B Drug Program. As stated by the Health Services and Resources Administration (HRSA,) the administering agency for the 340 B Program, it:

> "…**enables covered entities to stretch scarce federal resources as far as possible, *reaching more eligible patients and providing more comprehensive services*.**" [emphasis added]

NOSORH notes that a 2018 Health Affairs analysis acknowledges the HRSA statement of intent and concludes that the 340 B Program is *effective* in meeting this goal:

> https://www.healthaffairs.org/content/forefront/340b-drug-discount-program-fulfilling-its-original-purpose

NOSORH also notes that the Health Affairs analysis was released concurrent with the CMS decision to reduce 340 B Drug Program payments based upon its own interpretation of the purpose of the Program.

NOSORH believes that the *remedy* for multiple years of CMS underpayment should reflect the HRSA definition of the Program's intent.

Comments

NOSORH's specific comments on the NPRM follow.

Issue - Lump Sum Remedial Payments:

Discussion: CMS proposes to:

> ".. remedy our payment policy for 340 B acquired drugs for the period from CY 2018 through September 27th of CY 2022, which the Supreme Court found unlawful, [by making] one-time lump sum payments to affected 340B covered entities calculated as the difference between what they were paid for 340B drugs (ASP minus 22.5 percent or an adjusted WAC or AWP amount) during the relevant time period (from CY 2018 through September 27th of CY 2022) and what they would have been paid had the 340B payment policy not applied."

NOSORH believes that the lump sum payment is an appropriate response to the January 2023 remand of the District Court ordering CMS to determine the *proper* remedy for the underpayment amounts to 340 B Program participating hospitals in CY 2018 through CY 2022. NOSORH finds that a lump sum payment to affected 340 B Program participants is the basic remedy needed to offset the financial impact of CMS' mistakes and unlawful actions. The approach does *not*, however, fully compensate Program participants for the

financial impact of reimbursement delayed by up to four years. NOSORH addresses this supplemental financial impact in a separate section of these comments.

Comment: ***NOSORH supports the lump sum payment approach as a partial remedy for 340 B Program underpayments.*** Any other approach would be a continuation of underpayments and would cause further harm to affected 340 B Program participants.

Issue - Accounting for Beneficiary Cost-Sharing:

Discussion: CMS has recognized that affected 340 B Program participants would have received cost-sharing amounts from beneficiaries based upon the charged price for pharmaceuticals. The lower reimbursed charges for these drugs resulted in reduced cost-sharing revenues.

In the NPRM CMS excludes beneficiaries from any responsibility for cost-sharing for the remedial payment amounts. In addition, CMS will make payment to affected 340 B Program participants for what would have been received from beneficiaries as cost-sharing:

> "… the $9.0 billion payment amount includes $1.8 billion, an amount that is equivalent to what affected 340B covered entity hospitals would have collected from beneficiaries for these 340B-acquired drugs if the 340B payment policy had not been in effect."

Comment: ***NOSORH supports the proposed payment by CMS to affected 340 B Program participants of amounts equal to what would have been received from beneficiary cost-sharing.*** NOSORH believes that this is an important component for making them whole from damage resulting from CMS mistakes. ***NOSORH also supports the elimination of any beneficiary responsibility for cost-sharing on the remedial payments.***

Issue - Interest on Remedial Payments:

Discussion: CMS has addressed the question of interest to be paid on long-term 340 B Program underpayments with a single statement:

> "CMS also considered its authority to pay interest on the remedy payments but does not believe it has the authority to do so."

NOSORH believes that this is a shortsighted view of CMS' obligations for remedial payments. NOSORH believes that other Federal statute and regulation *require* interest to be calculated and paid on late payments under the 340 B Program. NOSORH believes that remedial payments are subject to the ***Prompt Payment Act***, as amended and its rules:

- 31 U.S.C. chapter 39;
- Section 1010 of Public Law 106–398;
- 114 Stat. 1654;
- Section 1007 of Public Law 107–107;
- 115 Stat. 1012; and
- https://www.federalregister.gov/citation/64-FR-52586.

NOSORH notes that, under the requirements of this Act:

> "The temporary unavailability of funds ***does not relieve an agency from the obligation to pay these interest penalties*** or the additional penalties required."

The payment of interest for the multi-year underpayments would contribute significantly to making whole affected 340 B Program participants, including rural hospitals. NOSORH also notes that the failure of CMS to make interest payments could result in additional litigation of this issue.

Comment: ***NOSORH recommends that CMS make provision to pay compounded interest on accrued underpayment amounts to affected 340 B Program participants*.**

Issue - Budget Neutrality of Remedial Payments:

Discussion: In the NPRM CMS asserts that the proposed remedy is subject to budget neutrality rules:

> "We believe these statutory requirements require that we maintain budget neutrality when making these remedy payments. To the extent these remedy payments are understood as a payment adjustment under section 1833(t)(2)(E) of the Act, they are subject to that section's budget neutrality constraints. And to the extent these payments are understood as a payment under section 1833(t)(14) of the Act, they are additional expenditures resulting from paragraph (t)(14) for years other than 2004 or 2005 and thus are subject to budget neutrality constraints under section 1833(t)(14)(H) of the Act."

CMS acknowledges that some previous OPPS payment policy changes have *not* been subject to budget neutrality considerations:

> "We acknowledge that, in the past, not all OPPS payment policy changes based on sections 1833(t)(14) and (t)(2)(E) of the Act have resulted in adjustments to the budget neutrality factor or actual expenditures from the Part B Trust Fund equaling zero in all circumstances."

NOSORH believes that the remedy is not a *payment adjustment*, but rather, a *Court-directed payment* to make whole affected 340 B Program participants who were negatively affected by CMS' mistaken and unlawful decisions. As such, NOSORH believes that such payments should be made *without* consideration of budget neutrality.

NOSORH notes that CMS has indicated in the NPRM some equivocation as to whether budget neutrality is required:

> "In the case of the remedy payments for the 340B payment policy, by contrast, we believe a budget neutrality adjustment is statutorily required and, ***even if not statutorily required, warranted as a matter of sound public policy.***"

NOSORH believes that budget neutrality is *not* required for these remedial payments, and further, NOSORH believes that sound policy requires public agencies to remediate the damage caused by their mistakes. This issue could be the focus of subsequent litigation, further extending the time period for resolution of this matter.

Comment: ***NOSORH recommends that CMS exempt remedial payments to affected 340 B Program participants from budget neutrality considerations.*** NOSORH believes that remedial payments should not be subject to budget neutrality considerations. Remedial payments could best be paid from one-time special appropriations or one-time transfers from the Medicare Trust Fund. *NOSORH recommends that CMS explore alternative sources such as these for offsetting the cost of remediation.*

Issue - Offsetting Payments:

Discussion: In the NPRM CMS proposes to offset the cost of remedial payments by:

> "…beginning in CY 2025, reduce all payments for non-drug items and services to all OPPS providers, except new providers as defined later in this section, by 0.5 percent each year until the total offset is reached (approximately 16 years). "

This approach is what CMS proposes to assure budget neutrality of the remedial payments. CMS targets for recoupment what the agency calls 'windfall' payments made over multiple years to OPPS providers resulting from CMS' own payment methodology.

NOSORH does not believe that previous payments are either windfall or improper payment amounts. They were legitimately billed by providers based upon rates and procedures established by CMS. Any overpayment by CMS results directly from the agency's own mistakes. ***To seek recoupment through lowered reimbursement over a 16-year period will harm all OPPS hospitals, including rural hospitals. It will penalize them for the agency's errors.***

NOSORH notes that over 200 rural hospitals have closed over the past few years, an issue of concern to Congress and the nation. In addition, recent studies have shown that an additional 600 rural hospitals are at risk of closure due to financial sustainability concerns. NOSORH believes that four years of underpayments from the 340 B Drug Program to participating rural hospitals contributed to this problem. In addition, NOSORH fears that the proposed 16 years of off-setting payment reductions could further exacerbate financial sustainability in rural hospitals.

Comment: ***NOSORH rejects the proposed approach to offsetting remedial 340 B Program payments through the long-term reduction of OPPS payments*.** As discussed previously, NOSORH believes that remedial payments should not be subject to budget neutrality considerations. Remedial payments could best be paid from one-time special appropriations or one-time transfers from the Medicare Trust Fund. *NOSORH recommends that CMS explore alternative sources such as these for offsetting.*

We appreciated the opportunity to submit comments on these important conditions of participation and hope you find value in the outlined recommendations.

Let me know if you have questions, would like discussion, or if I may be of assistance. Thanks so much.

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