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CMS Cuts Payments for Most 340B Drugs

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On the Subject

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Summary

On November 1, 2017, the US Department of Health and Human Services released a Final Rule implementing a payment reduction for most covered outpatient drugs billed to Medicare by 340B-participating hospitals from the current Average Sales Price (ASP) plus 6 percent rate to ASP minus 22.5 percent, which represents a payment cut of almost 30 percent. The payment reduction is effective January 1, 2018, for all 340B-participating hospitals paid under the Medicare Hospital Outpatient Prospective Payment System (OPPS) with the exception of rural Sole Community Hospitals, PPS-excluded Children's Hospitals and PPS-excluded Cancer Hospitals.

Savings to the Medicare program from the payment cut will be redistributed in a budget-neutral manner to all hospitals paid under OPPS through an increase in the payment rate for non-drug items and services.

In Depth

As part of the Calendar Year (CY) 2018 updates to the Medicare Hospital Outpatient Prospective Payment System (OPPS), the US Department of Health and Human

Services Centers for Medicare and Medicaid Services (CMS) will decrease Medicare Part B payments to hospitals for 340B drugs by almost 30 percent. The final rule, released on November 1, 2017 (Final Rule), implements the proposed rule, released on July 13, 2017 (Proposed Rule), with limited changes, including the exception of rural Sole Community Hospitals (SCHs), PPS-excluded children's hospitals (Children's Hospitals) and PPS-excluded cancer hospitals (Cancer Hospitals) from the reduction in payment.

CMS has stated that the purpose of the payment reduction is to slow growth in the 340B program, shift trends of increasing amounts paid by Medicare for outpatient hospital drugs, and reduce Medicare beneficiary cost-sharing. Critics of the payment cuts responded to the Proposed Rule with comments emphasizing that the policy will be devastating to hospitals participating in the 340B Program and will challenge their ability to serve low-income patients and other vulnerable populations.

Under the Final Rule, Medicare payments for most separately payable Part B drugs dispensed to hospital outpatients, including those purchased through the Prime Vendor Program, will be subject to a reduction in payment from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent, effective January 1, 2018. The reduction will not apply to vaccines or drugs with transitional "pass-through" payment status. CMS derived the reduction from a May 2015 report to Congress from the Medicare Payment Advisory Commission (MedPAC), which found that ASP minus 22.5 percent represents the average minimum discount that 340B-participating hospitals receive for separately payable drugs under OPPS.

Based on CY 2016 claims data, CMS estimates that the Final Rule will result in a reduction of as much as $1.6 billion in OPPS payments for drugs subject to the payment cut, up $700 million from the original projection in the Proposed Rule based on updated data. CMS indicates it will implement the payment policy in a budget neutral manner such that the Medicare program savings generated from the cut in drug payments will be used to increase payments for all other services paid under OPPS, and applicable to all hospitals (including hospitals that are not eligible to participate in the 340B Program, such as for-profit hospitals). CMS estimates that the redistribution in payments will result in an increase in other payments under OPPS by approximately 3.2 percent (up from the original projection of 1.4 percent in the Proposed Rule).

The 340B payment cuts in the Final Rule are limited to certain drugs that are separately payable by Medicare Part B under OPPS. Therefore the payment reduction does not apply to all 340B-participating hospitals or all 340B drugs dispensed by hospitals subject to the payment cut. Critical access hospitals are not subject to the payment change because they are not paid under OPPS. Neither are hospital outpatient services furnished at off-campus outpatient locations subject to payment provisions under Section 603 of the Bipartisan Budget Act of 2015, which will continue to be paid under the Medicare Physician Fee Schedule rate for outpatient drugs (ASP + 6 percent), subject to CMS review of this payment policy in future years.

Further, the Final Rule does not directly affect payments for 340B drugs dispensed through most 340B contract pharmacy arrangements, 340B drugs that are "packaged" by Medicare into the Part B payment for a related procedure, or certain

340B drugs dispensed to outpatients who are subsequently admitted as inpatients. CMS also excepted rural SCHs, Children's Hospitals and Cancer Hospitals from the reduction, even though they are paid under OPPS.

Beginning on January 1, 2018, the Final Rule requires *all* 340B hospitals paid under OPPS to report a modifier, regardless of whether the 340B hospital is exempt from the 340B payment adjustment. Providers who are not excepted from the 340B payment adjustment will report modifier JG (drug or biological acquired with 340B Drug Pricing Program Discount) to identify if a drug was acquired under the 340B Program, while those providers who are excepted (rural SCHs, Children's Hospitals and Cancer Hospitals) should report the informational modifier (TB). The requirement to use the JG modifier applies only to OPPS separately payable drugs (status indicator K) and does not apply to vaccines (status indicator L or M) or drugs with transitional pass-through payment status (status indicator G). Use of modifier TB will not trigger a payment adjustment, and these providers will continue to receive ASP plus 6 percent for separately payable drugs furnished in CY 2018, even if such drugs were acquired under the 340B Program. CMS indicates that the informational modifier TB is intended to facilitate the collection and tracking of 340B claims data by CMS for OPPS providers that are excepted from the payment adjustment.

Analysis

Although the initial proposal to cut Medicare hospital payments for 340B drugs took many stakeholders by surprise, both Congress and the new administration recently have been examining a variety of drug pricing issues, including concerns regarding growth in the 340B program. The adoption of the payment cut in the Final Rule with minimal revisions from the Proposed Rule despite significant 340B stakeholder objection provides insight into the current political environment for the 340B Program and the direction that future payment policies and legislative proposals may take. Upon release of the Final Rule, America's Essential Hospitals, the American Hospital Association and the Association of American Medical Colleges immediately signaled their intent to sue CMS based on the belief that the agency has overstepped its statutory authority to reduce drug payments for a subset of hospitals.

In addition to the payment reduction's potentially significant financial consequences, the requirement for all 340B hospitals paid under OPPS to utilize modifiers by January 1, 2018, may pose an administrative and financial burden to already cost-strained providers. These providers serve low-income and needy populations, and the ability of these facilities to acquire the proper pharmacy tools and software technology to support drug inventory management by such a tight deadline may pose significant challenges. Various commenters raised these concerns in response to the Proposed Rule, and CMS responded that use of the modifiers is aligned with the modifier requirement already mandated in several state Medicaid programs. CMS therefore believes that this approach will promote consistency between the two programs and will not pose a significant administrative burden.

It is not clear, however, why CMS did not opt to require use of the existing claim

modifier (UD) used by most state Medicaid programs and commercial payors that require 340B claim identifiers to identify 340B drugs. If state Medicaid programs and other payors do not adopt the new Medicare modifiers to identify 340B drugs, the obligation to report different modifiers according to payor will likely create even more administrative burdens for 340B hospitals.

This Final Rule represents a critical change in Medicare policy affecting the continued viability of the 340B Program and CMS authority to make material payment changes through sub-regulatory guidance.