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Submitted electronically via Regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1695–P
P.O. Box 8013
Baltimore, MD 21244–1850

Re: CMS–1695–P; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Administrator Verma:

The Pew Charitable Trusts (Pew) is pleased to offer comments on the CY 2019 Hospital Outpatient Prospective Payment System Proposed Rule ("proposed rule"). Pew is an independent, nonpartisan research and public policy organization dedicated to serving the American public. Our drug spending research initiative is focused on identifying policies that would allow public programs to better manage spending on pharmaceuticals while ensuring that patients have access to the drugs that they need. Our antibiotic resistance project supports policies that would spur the creation of new antibiotics, reduce the need for antibiotics in food animals, and improve antibiotic prescribing practices in human health care settings.

Pew commends the Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) for its commitment to addressing drug spending and to promoting higher-quality care for Medicare beneficiaries through the Hospital Outpatient Quality Reporting Program (OQR), which we believe can help curb inappropriate antibiotic prescribing across healthcare settings. Our comments focus on the proposed rule's Request for Information (RFI) on Leveraging Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model; we also offer comments on the Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital, and the proposal to reduce reimbursement for drugs or biologicals during the initial sales period; finally, we recommend that CMS consider including antibiotic-use related measures in future Hospital OQR Program measure sets.

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Leveraging Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Pew commends CMS for its commitment to reducing spending on drugs in the Part B program, one of the fastest growing cost centers in Medicare. In Pew's response to the Administration's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,[1] we highlighted how the Secretary may be able to use existing CAP authority to encourage competition in the Part B program without requiring the CAP vendor to take possession or title to individual drugs. In our comments here, we offer additional insight on this model in response to the more detailed questions presented in the RFI. Our comments are limited to how the various approaches may affect drug spending and we do not offer comment on the operationalization of any policy.

Included Providers and Suppliers

In order to achieve the greatest possible reduction in Medicare Part B drug spending, no providers should be excluded from participating in a CAP-like model. Excluding a group of providers based on site of care or specialty could diminish vendor bargaining power and manufacturer willingness to negotiate discounts for drugs used by those providers, limiting Medicare savings.

The misaligned financial incentives in Medicare Part B payment for drugs apply across all specialties and provider groups. While providers in certain therapeutic areas may derive a significant portion of their Medicare revenue from drug reimbursement, this revenue is not related to the quality of clinical care provided. As the RFI notes, "because the 6-percent add-on results in an increased Medicare payment for a higher-cost drug relative to a lower-cost drug, the use of more expensive drugs may generate more revenue for a health care provider … Meanwhile, the ASP-based methodology creates no direct incentives for furnishing high-value drug therapies."[2]

Incentives and protections to participate in a CAP-like model should encourage high-value care and be de-linked from the price of drugs. Under the Medicare Part D program, providers do not generate revenue from prescribing medications, and the provision of provider-administered drugs under the Part B program should similarly de-link provider revenue from the clinical choice to prescribe a specific drug. There are a range of approaches that could be used to incent participation in a CAP-like model. First, providers could be permitted to share in any savings generated through reduced spending on drugs. The Drug Value Program proposed by the Medicare Payment Advisory Commission would allow participating providers to share in savings generated by the program.[3] However, any use of a shared savings program should continue to de-link physician revenue from a drug's list price (or discounts realized off list price), deterring manufacturers from increasing list prices to encourage utilization. Such an approach could be

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[1] The Pew Charitable Trusts. "Pew Responds to White House's Drug Pricing Blueprint Information Request," July 16, 2018, http://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2018/07/16/pew-responds-to-white-houses-drug-pricing-blueprint-information-request.

[2] 83 Fed. Reg. 37213

[3] Medicare Payment Advisory Commission, "Report to the Congress: Medicare Payment Advisory Commission, "Report to the Congress: Medicare Payment Policy" (2017), http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.

combined with a requirement that providers follow clinical guidelines to avoid creating incentives to reduce utilization of necessary therapies. Another way to spur participation is through the creation of a payment modifier that that increases providers' reimbursement rate for all services billed under the Medicare Part B program, regardless of whether the provider prescribes a Part B drug. Under this approach, by electing to participate in the CAP-like program, the provider will forego the ability to earn revenue linked to the prescription of a Part B drug (aside from administration fees); this tempers any financial incentive to prefer a clinical course that includes a Part B drug over a Part D drug or a non-drug approach to treatment. This structure would harmonize provider incentives for drugs paid under both the Part B and Part D programs. Alternatively, a payment modifier could be created to increase payments to participating providers for the act of administering a drug but not for the product itself. While providers may see a reduction in Medicare payments if they opt out of the current reimbursement methodology, each of these would partially offset those losses and incent participation. After an evaluation period of the CAP-like model, if this approach is successful in reducing Medicare Part B drug spending without reducing quality of care, CMS should consider reducing payments to providers that do not participate in the CAP-like model, thereby encouraging them to participate.

In the beneficiary cost-sharing section below, we offer additional comments on how reduced cost-sharing for beneficiaries receiving services from a provider in the CAP-like model could provide an incentive to select providers participating in the CAP-like model, creating a market-driven approach to encouraging provider participation.

Included Drugs and Biologicals

All drugs and biologicals eligible for reimbursement under Medicare Part B should be considered eligible for inclusion in a CAP-like model. In an initial model, however, drug categories where there are multiple therapeutically similar competing products would be an appropriate starting point. For example, vendors may be able to easily implement price negotiations for innovator biologics and their associated biosimilars. Because there is no clinically meaningful difference between biosimilars and their reference product, there should be limited clinical concern about preferring one treatment over another for patients initiating therapy. Developers of biosimilars have reduced Average Sales Prices compared to innovator products,[4] signaling an intent to compete on price rather and negotiate discounts for preferential treatment.

While value-based purchasing (VBP) strategies may help to negotiate lower costs for certain drugs, Medicare should view value-based metrics as a price-ceiling rather than a price-floor. In a competitive marketplace, manufacturers should be willing to offer prices below the value of a drug so long as marginal revenues exceed marginal costs. Relying on a value-based metric could lead to manufacturers tacitly setting prices at the value-based price rather than competing below the value-based price for preferential treatment. Evidence from other countries that have invested in VBP mechanisms indicates

[4] Centers for Medicare & Medicaid Services, "Medicare Part B Drug Spending Dashboard," https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2018ASPFiles.html.

only limited financial savings.[5] Medicare should instead focus on using clinically-appropriate utilization management techniques to encourage manufacturer competition for discounts below a value-based price.

When a drug market has some competition, agreeing to pay for drugs based on value may actually lead to increased drug spending. Consider the hepatitis C treatment market – the availability of multiple brand competitors resulted in prices falling 45-55% within only two years of release,[6] even though the drugs were generally cost-effective at launch prices.[7,8] If value or cost-effectiveness were used as a metric to pay for these drugs, spending would likely be significantly higher.

Under a CAP-like model, VBP may be appropriate for drugs or biologicals without competition from therapeutically similar products. If vendors under a CAP-like model are allowed to perform their own value assessments as part of a negotiation strategy, this could foster additional competition across vendors. Vendors should be required to make their value assessments publicly available for review to promote high quality assessments and provide commercial and other payors with information that may reduce costs outside of the Medicare program. Allowing vendors to perform their own value assessments could create a broader market for value assessments; while value assessments are currently performed by organizations such as the Institute for Clinical and Economic Review (ICER) and could be relied on by vendors, these organizations may be limited in how many assessments they can conduct. Vendor-led value assessments could increase the breadth and depth of assessments performed, providing more information to both Medicare and the broader healthcare field.

Beneficiary Cost Sharing, Protections, and Fiscal Considerations

Patients should share in any savings generated under a CAP-like model. Under the Medicare Part D program, Medicare beneficiaries with higher cost-sharing have lower treatment initiation and longer delays in treatment initiation that beneficiaries with lower cost-sharing.[9] Reducing cost-sharing in the Medicare Part B program under a CAP-like model may increase beneficiary treatment initiation, which has the potential to increase costs. However, beneficiary preference for lower cost-sharing may drive beneficiaries to select providers that participate in the CAP-like model, encouraging more providers to participate and generate further Medicare savings. Assuming that any increased treatment initiation is clinically appropriate and delivered at lower costs under a CAP-like model, any utilization increases from

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[5] Navarria, Andrea, et al. "Do the current performance-based schemes in Italy really work? 'Success fee:' a novel measure for cost-containment of drug expenditure." Value in Health 18.1 (2015): 131-136.
[6] Dan, C. "In Case You Missed It – 2016 Study Compared Hepatitis Treatment Costs," HHS Office of HIV/AIDS and Infectious Disease Policy, Jan. 3, 2017, https://www.hhs.gov/hepatitis/blog/2017/1/3/icymi-2016-study-compared-hepatitis-c-treatment-costs.html.
[7] Tice, J. A., et al. "The comparative clinical effectiveness and value of novel combination therapies for the treatment of patients with genotype 1 chronic hepatitis C infection: a technology assessment," Institute for Clinical and Economic Review, Jan. 30, 2015, https://icer-review.org/wp-content/uploads/2016/01/CTAF_HCV2_Final_Report_013015.pdf.
[8] Chahal, Harinder S., et al. "Cost-effectiveness of early treatment of hepatitis C virus genotype 1 by stage of liver fibrosis in a US treatment-naive population." JAMA Intern Med. 176.1 (2016): 65-73.
[9] Li, Pengxiang, et al. "Association of high cost sharing and targeted therapy initiation among elderly Medicare patients with metastatic renal cell carcinoma." Cancer Medicine 7.1 (2018): 75-86.

lower cost-sharing under a CAP-like model should not significantly affect Medicare spending and may be offset by increased provider participation.

If reduced drug prices available under a CAP-like model are used to set beneficiary cost-sharing payments, beneficiary costs would be reduced by the same magnitude as the overall price reduction. However, if the reduced drug prices under a CAP-like model are not significant reductions, reduced beneficiary cost-sharing may not be sufficient to encourage beneficiaries to select providers that are participating in the CAP-like model, reducing overall savings to Medicare.

For example, if a manufacturer offers a 20% discount on a $1,000 drug and beneficiaries remain liable for 20% of the discounted cost, a beneficiary's cost sharing would only be reduced by $20 ($200 to $180), even though Medicare would save $180; the $20 savings to the beneficiary may not be sufficient incentive for the beneficiary to change her provider to one participating in the CAP-like model. If the reduction in cost sharing is inadequate to affect patient choice of provider, the policy would also not be sufficient to incent providers to participate in order to attract or retain patients. If Medicare reduced the beneficiary's cost-sharing to 10% of the drug's cost, the beneficiary would save $110 ($200 to $90) and Medicare would still save $90, even after covering the reduction in the beneficiary's cost-sharing. If cost-sharing were eliminated or reduced to a nominal amount, Medicare savings on a per-drug basis may be reduced, but Medicare may still see substantial overall savings from reductions in use of more expensive drugs (e.g., a $1,000 drug is preferred by the vendor over a $2,500 drug) or more clinically-appropriate use of drugs.

Model Vendors

The role of the CAP vendor would be improved by aligning the vendor model with the drug acquisition and reimbursement practices commonly used in the private sector. Under this model, providers acquire medications from the same suppliers and maintain a single inventory for all their patients. The prior CAP relied on discounts acquired at the point of sale by the CAP vendor to reduce costs, but in the commercial sector, discounts are often realized by payers, such as insurers and Pharmacy Benefit Managers (PBMs), rather than entities involved in the physical transfer of the drug, such as wholesalers. CMS should consider a broad range of possible vendors, including PBMs, group purchasing organizations, wholesalers, integrated health systems, specialty pharmacies, and insurers, so long as the vendor is able to perform the required functions. Some possible vendors may be better suited to manage utilization and negotiate prices under a CAP-like model for particular therapeutic areas, and CMS may consider issuing separate CAP-like model bids or allowing a vendor to only bid for certain drug classes within the CAP-like model.

Because providers typically treat patients with a mix of different insurance coverage, including private insurance, Medicare and Medicaid, providing discounts to payers rather than supply chain entities allows the provider to maintain a single drug inventory for all patients. Requiring a provider to acquire drugs for its patients at different prices and from different vendors based on insurance coverage would

increase administrative burden. To avoid this issue, a CAP-like model could leverage the existing system, avoiding a possible disincentive (separate Medicare inventory) to provider participation.[10]

In designing vendor service areas and selecting a vendor, CMS should consider how the level of vendor competition may encourage or discourage manufacturers from negotiating discounts or developing products that may be candidates for negotiation. This consideration should also assess the size of the non-Medicare market for drugs included in a CAP-like model. For example, a national vendor could exercise significant market power to prioritize the use of one drug relative to competitors in the therapeutic area and obtain a large discount on that drug; however, if the majority of care in that therapeutic area is within the Medicare Part B program and utilization shifts to one drug, manufacturers may be discouraged from developing products to compete in the space. Consider biosimilars – if a nationwide vendor in a CAP-like model selects only one biosimilar product as the preferred treatment for an age-related condition that primarily affects Medicare beneficiaries, other manufacturers may be unwilling to develop a competing biosimilar if only one product will see significant utilization. However, if there are multiple vendors in a CAP-like model, there would be more opportunities for a manufacturer's product to be selected as the preferred treatment, which may foster a more robust and competitive marketplace.

If a CAP-like model does not reimburse providers for the acquisition cost of included drugs but instead provides drug to the provider for administration, model vendor selection should consider how a provider could use existing office stock of a drug without needing to wait for drug to be provided by the vendor to the provider. Virtual inventory replenishment systems, such as those often used by providers participating in the 340B Drug Discount Program,[11] may be a solution. Under this approach, the provider would initially acquire drug outside of the CAP-like program; when a drug is administered under the CAP-like program, the provider would record that administration in her virtual inventory system and would replenish her stock with drug acquired under the CAP-like program (at $0 acquisition cost to the provider). To facilitate this model, CMS may consider selecting vendors that can supply providers with drug for both Medicare and non-Medicare patients, easing provider inventory management. CMS may also consider operating a CAP-like model as a demonstration project rather than under the CAP authority to avoid requiring a vendor to take physical control of a drug.

As the RFI notes, under the existing Medicare Part B structure, "the use of more expensive drugs may generate revenue for a health care provider."[12] This incentive structure could be exacerbated if vendors more are compensated based on the list price of included drugs or any savings off the list price. Instead, CMS may consider compensating vendors on a unit basis, paying a per-unit fee commensurate with fees realized by the vendor in their commercial lines of business. This model is similar to the compensation

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[10] MedPAC, "Medicare Part B Drug Payment Policy Issues," 2017, http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0.

[11] Wright, S. "Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431," Department of Health and Human Services Office of Inspector General (Feb. 4, 2014). https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. (discussing various 340B inventory management systems).

[12] 83 Fed. Reg. 37213

structure for Part D plans,[13] where insurers receive a per-member profit based on disclosures of per-member profits under the insurer's commercial plans. CMS could structure this per-unit payment on the units of drugs dispensed, the number of providers enrolled in the vendor's CAP-like program, or the number of beneficiaries treated. Basing the payment on the number of providers enrolled or beneficiaries treated may discourage excess drug utilization, allowing the vendor to encourage alternative care modalities when clinically appropriate. For example, vendors could compete for provider participation by distributing savings achieved back to providers; providers would choose to enroll with the vendor anticipated to achieve the greatest savings, yet the vendor would only be compensated on a per-physician enrollment basis. Providers would agree to follow the care management practices outlined by the vendor, allowing providers to select vendors with more aggressive drug price negotiation or utilization management practices in exchange for higher compensation. This would foster competition among vendors on both cost-savings and provider support, which may encourage greater vendor marketplace competition through additional product differentiation.

Vendor compensation should also recognize any remuneration vendors receive from pharmaceutical manufacturers or other parties, requiring disclosure of any remuneration, including remuneration outside of the CAP-like program, to ensure that such remuneration is not increasing Medicare spending. If the vendor is a supply chain entity already involved in the distribution of drugs under the Medicare Part B program, such as a wholesaler or specialty pharmacy, the vendor may already receive manufacturer bona fide service fee payments for distribution services; Medicare should not compensate the vendor for these services if the vendor is receiving manufacturer payments for the same services. Vendors should also be required to disclose all remuneration from manufacturers outside of the CAP-like program to determine whether any outside remuneration could be influencing the vendor's decisions in the CAP-like program, such as above-market service fees for other products by the manufacturer in exchange for preferring a product of the manufacturer under the CAP-like program. While such remuneration may already be subject to penalties under the False Claims Act and the Anti-Kickback Statute, disclosure of this information and regular auditing by Medicare may reduce the need for after-the-fact enforcement, resulting in lower Medicare spending. Medicare may also consider imposing a fiduciary duty on vendors under a CAP-like program, requiring that the vendor conduct all activities under the program in the best interests of Medicare and beneficiaries and not the vendor.

In addition to negotiating discounts from manufacturers, vendors under a CAP-like model may also be able to achieve savings through reducing medication waste. One study found savings of up to $2 billion annually from reducing waste from unused cancer treatments in Medicare Part B.[14] A vendor that safely re-packaged medication under appropriate quality standards could achieve savings from reducing waste in addition to negotiating discounts from manufacturers; this vendor could also supply providers with re-packaged medication for non-Medicare patients, reducing costs for other payors. Alternatively, the

[13] 42 C.F.R. § 423.265

[14] Bach, P.B., Conti, R.M., Muller, R.J., Schnorr, G.C. and Saltz, L.B., 2016. Overspending driven by oversized single dose vials of cancer drugs. BMJ: British Medical Journal (Online), 352.

existence of a vendor repackaging program could encourage manufacturers to market smaller vials of medications to avoid waste, achieving similar savings.

Manufacturer Participation

To ensure that manufacturers participate in a CAP-like model, CMS may consider requiring manufacturers to engage in good-faith negotiations with vendors in order for any of the manufacturer's products to be eligible for reimbursement under the Part B program; this is similar to the requirement that a manufacturer must provide Medicaid rebates on all of its products in order for any product to be eligible for Medicaid or Medicare Part B coverage.[15] Without the requirement to engage in good-faith negotiation, all manufacturers of competing products in a therapeutic area may elect not to negotiate with vendors, effectively avoiding competition. One model for this requirement could be the solicitation system under the Department of Veterans Affairs (VA) Federal Supply Schedule negotiations, where manufacturers are required to provide certain data and negotiate drug prices with the VA for certain government purchasers.[16]

Some manufacturers may express concern that discounts provided under a CAP-like model could be included in government price reporting requirements, including the calculation of Average Manufacturer Price (AMP) and Best Price under the Medicaid Drug Rebate Program. Provider-administered drugs under the Medicare Part B program, by their nature, are likely to be calculated under an alternative AMP methodology (commonly referred to as "5i AMP").[17] Under this methodology, discounts to a vendor under a CAP-like program would likely be included in AMP, reducing AMP.[18] If AMP is reduced, this would reduce manufacturer rebate liability in the Medicaid program, which could increase Medicaid spending. For example, assume that a vendor negotiates a discount on a $1,000 drug and that this discount reduces the AMP on the drug from $1,000 to $900; this reduction in AMP would reduce the manufacturer's Medicaid rebate liability by 10%, from $231 to $208 (the Medicaid rebate for brand name drugs starts at 23.1% of AMP).[19] Because providers caring for Medicaid beneficiaries will still be reimbursed by Medicaid based on the $1,000 price, Medicaid's net costs for the drug will increase from $769 to $792 ($1,000 minus $231 vs $1,000 minus $208). To avoid this increase in Medicaid spending, CMS may consider excluding sales and discounts associated with the CAP-like program from AMP calculations.

Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

In our comments on the 2017 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Proposed Rule, we highlighted possible unintended consequences of reducing payment to 340B-eligible hospitals for drugs purchased at the 340B price.

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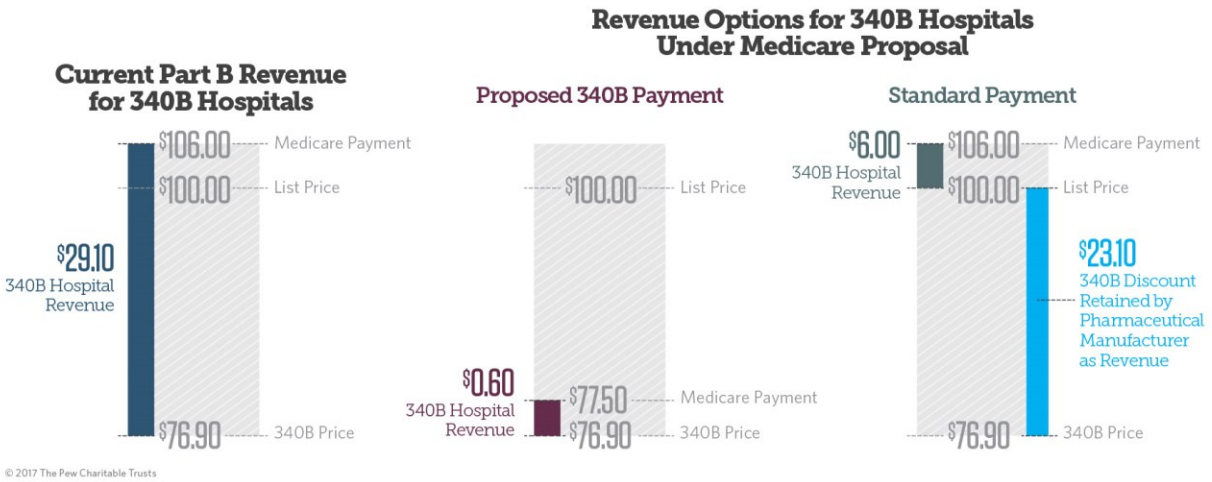
[15] 42 U.S. Code § 1396r–8(a)(1)
[16] U.S. Department of Veterans Affairs, Office of Procurement, Acquisition and Logistics (OPAL), "Schedule 65 I B Drugs, Pharmaceuticals, & Hematology Related Products," https://www.va.gov/opal/nac/fss/pharmaceuticals.asp.
[17] 81 Fed. Reg. 5237
[18] 42 C.F.R. § 447.504(d)
[19] 42 U.S.C. § 1396r–8(c)

Most notably, reducing payments from ASP plus 6 percent to ASP minus 22.5 percent for 340B purchased drugs could encourage hospitals to selectively purchase certain drugs at higher prices outside of the 340B program to maximize revenue. For drugs that have not taken price increases greater than the rate of inflation, hospitals would likely see higher revenue from purchasing the drug at full price and receiving the increased reimbursement rather than purchasing at the discounted 340B price and receiving lower reimbursement. In this situation, Medicare will not realize any reduced spending and the 340B discount will be retained by the manufacturer. We reproduce a graphical analysis from our 2017 comments outlining this potential revenue impact below.

Potential Revenue Impact of Medicare's Proposed Payment Reduction to 340B Hospitals

Medicare's proposal to reduce payments to 340B hospitals would decrease 340B hospital revenue. Under this proposal, for some drugs, 340B hospitals would receive greater revenue by purchasing the drug at the list price instead of the discounted 340B price, receiving the standard Medicare payment instead of the proposed reduced Medicare payment. In these situations, manufacturers would retain the 340B discount as revenue.



While the reduced payment policy to 340B hospitals has only been in effect since January 2018, CMS may have data about the frequency at which 340B-eligible hospitals are submitting non-340B claims for reimbursement to Medicare Part B, which could provide insight on the magnitude of savings that may be achieved by extending this policy to off-campus locations. However, hospitals' limited experience with the reduced payments may also mean that they have not fully optimized their purchasing to selectively use the 340B program, overstating the potential savings from expanding the policy. CMS could also consider alternate reimbursement methodologies for 340B-purchased drugs, such as a six percent add-on payment to the estimated 340B cost (ASP-22.5%) that would discourage hospitals from selectively purchasing some drugs outside of the 340B program.

Payment for Drugs or Biologicals During an Initial Sales Period

We concur with CMS' proposal to reduce payment, from Wholesale Acquisition Cost (WAC) plus six percent to WAC plus three percent, for drugs or biologicals during an initial sales period during which

Average Sales Price (ASP) data is unavailable. This reduction will more closely align reimbursement with acquisition cost and may reduce any incentive to select a drug or biological based on the amount of reimbursement received.

Hospital Outpatient Quality Reporting Program – Antibiotic-Use Related Measure

Antibiotics are essential to the practice of modern medicine – from treating common infections to enabling lifesaving procedures such as organ transplantation. All antibiotic use, whether appropriate or not, contributes to the growing threat of antibiotic resistance. Improved antibiotic prescribing practices across all healthcare settings is needed to minimize this threat and preserve the effectiveness of these important drugs. We recommend that CMS consider including antibiotic-use related measures in future Hospital Outpatient Quality Reporting (OQR) Program measure sets in order to help spur improved antibiotic prescribing practices in these health care facilities.

Over the past four years, Pew has partnered with the Centers for Disease Control and Prevention (CDC) to gain a better understanding of how antibiotics are prescribed in outpatient health care settings. Analysis of two nationally-representative outpatient health care surveys – the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) – found that at least 30% of outpatient antibiotic prescriptions are unnecessary, amounting to about 47 million prescriptions per year.[20] Of these unnecessary prescriptions, the vast majority (nearly 34 million prescriptions per year) were due to unnecessary prescribing for acute respiratory conditions – such as bronchitis and viral upper respiratory tract infections. Further analysis of NAMCS and NHAMCS showed that, for three conditions commonly treated in outpatient settings – sinus infections, middle ear infections, and pharyngitis – only 52% of patients who were treated with antibiotics received recommended first-line drugs based on established practice guidelines.[21] Another study looking at antibiotic prescribing practices by different types of outpatient facilities found that 25% emergency department patients who were diagnosed with an acute respiratory condition that did not warrant antibiotic use received antibiotics against practice guidelines.[22] This research has found a clear need for improved outpatient antibiotic prescribing practices – including in hospital-based facilities such as emergency departments.

Antibiotic stewardship efforts aim to ensure that antibiotics are only prescribed when needed and that, when prescribed, the patient receives the most appropriate antibiotic at the correct dose and duration of therapy. The expansion of stewardship efforts nationwide is needed to improve outpatient antibiotic

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[20] Katherine Fleming-Dutra et al., "Prevalence of Inappropriate Antibiotic Prescriptions Among US Ambulatory Care Visits, 2010-2011," Journal of the American Medical Association 315, no. 17 (2016): 1864-73, https://www.ncbi.nlm.nih.gov/pubmed/27139059.

[21] Adam L. Hersh et al., "Frequency of First-line Antibiotic Selection Among US Ambulatory Care Visits for Otitis Media, Sinusitis, and Pharyngitis. JAMA Internal Medicine 176, no. 12 (2016): 1870-1872, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2571613.

[22] Danielle Palms et al., "Comparison of Antibiotic Prescribing in Retail Clinics, Urgent Care Centers, Emergency Departments, and Traditional Ambulatory Care Settings in the United States, 2014," JAMA Internal Medicine, July 16, 2018, http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/10.1001/jamainternmed.2018.1632.

prescribing practices. One of the CDC's core elements for an effective outpatient stewardship program involves the tracking and reporting of antibiotic prescribing data.[23] These data provide a benchmark for current practice, help identify areas for improvement, and provide the foundation for measuring the impact of antibiotic stewardship efforts.

In order to support this important aspect of antibiotic stewardship, we recommend that CMS consider including antibiotic use measures within the Hospital OQR program. Validated antibiotic use measures currently exist, such as the Healthcare Effectiveness Data and Information Set (HEDIS) measures for avoiding antibiotic use in patients with bronchitis and viral upper respiratory infections. Antibiotic use measures have already been incorporated into the Merit-based Incentive Payment System (MIPS) as part of its quality performance measurements. While the inclusion of these measures in MIPS can encourage clinicians to improve their antibiotic prescribing, the addition of similar measures to the Hospital OQR program can further enhance antibiotic stewardship efforts at the facility level. These measures could incentivize hospitals to expand current inpatient stewardship programs and commit available resources to assist outpatient providers in reducing inappropriate antibiotic use.

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We appreciate the opportunity to respond to this RFI and commend the Administration for its attention to drug spending and to promoting higher-quality care for Medicare beneficiaries through the Hospital OQR Program, which we believe can help curb inappropriate antibiotic prescribing across healthcare settings. Should you have any further questions, please contact me by phone at 202-540-6392 or via email at acoukell@pewtrusts.org.

Sincerely,

Allan Coukell, BScPharm
Senior Director, Health Programs
The Pew Charitable Trusts

[23] Centers for Disease Control and Prevention, The Core Elements of Outpatient Antibiotic Stewardship, accessed Aug. 22, 2018, https://www.cdc.gov/antibiotic-use/community/pdfs/16_268900-A_CoreElementsOutpatient_508.pdf.