May 6, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Attention: CMS-1670-P
Submitted electronically to https://www.regulations.gov

Re: CMS-1670-P – Medicare Program; Part B Drug Payment Model; Proposed Rule

Dear Mr. Slavitt,

The Alliance of Community Health Plans (ACHP) commends CMS for proposing the Medicare Part B Drug Payment Model, and is pleased to comment on the proposed rule published in the *Federal Register* on March 11, 2016. We support moving forward with the proposed demonstration and submit recommendations in this letter for your consideration.

ACHP is a national leadership organization that brings together innovative health plans and provider groups that are among America's best at delivering affordable, high-quality coverage and care in their communities. Members are non-profit organizations or subsidiaries of non-profit health systems. They provide coverage for more than 18 million Americans in the commercial market and for Medicare, Medicaid, and federal, state, and local public employees. The community-based and regional health plans and provider organizations that belong to ACHP improve the health of the communities they serve and are on the leading edge of patient care coordination, patient-centered medical homes, accountable health care delivery, information technology use, and other innovations to improve affordability and the quality of care.

Introductory Comments

ACHP supports CMS' efforts to address the rising cost of Medicare Part B drugs through the proposed demonstration of a new Average Sales Price (ASP) payment methodology and the application of certain value-based purchasing (VBP) tools. We share CMS' concern that the current ASP plus 6 percent add-on methodology can create a financial incentive for the use of more expensive drugs when lower priced, but equally effective, alternatives are available. As CMS and researchers have pointed out, the 6 percent add-on for higher cost drugs may result in greater provider revenue and profit margin than the same

1825 Eye Street, NW, Suite 401 | Washington, DC 20006 | p: 202.785.2247 | f: 202.785.4060 | www.achp.org

add-on for a lower cost but equally effective drug. While providers weigh a number of clinical considerations in making treatment decisions, financial considerations also play a role. We appreciate that CMS is proposing to address this issue by testing a new payment methodology, and that CMS is coupling it with value-based strategies to further encourage better care and smarter spending. The goal should be aligning financial incentives and clinical information so that patients receive the right drug at the right time.

The escalating costs of prescription drugs and biologics threaten the stability of both public and private insurance coverage. Moreover, drug costs contribute to economic hardship for many Americans, some of whom forego or underuse prescribed medications because their costs have become unaffordable. As noted below, ACHP believes the greatest responsibility for spending increases lies with the manufacturers, but the proposed demonstration is a significant step in the right direction. Importantly, the demonstration incorporates a multi-pronged approach addressing reimbursement, benefit design and evidence-based decision tools. We appreciate that CMS has engaged stakeholders in this necessary discussion.

Pricing is the Core Problem: ACHP continues to believe that the major responsibility for unsustainable drug spending remains with the pharmaceutical manufacturers. The rising spending for drugs and biologics is a system-wide concern, and a major contributing factor are the prices set by manufacturers. Manufacturers need to be transparent about their research and development, marketing, advertising and other costs in getting a drug to market and setting prices that reasonably reflect the true costs. ACHP encourages CMS to work further with stakeholders to address the pricing side of the ledger with the expectation that this will enable it to move beyond modifications in the Average Sales Price (ASP)-based payment methodology.

In ACHP's tracking of drug costs for our member plans, we have seen especially rapid cost increases for specific categories and classes of Part B drugs. Our plans' experiences reflect those of health plans more generally. For example, the annual cost of treating rheumatoid arthritis in the U.S. is expected to increase by almost 50 percent from 2013 to 2020, reaching over $9 billion. New drugs to treat multiple sclerosis are launching at costs that are as much as 25 to 60 percent higher than the price of existing drugs.

The introduction in recent years of breakthrough but very high cost treatments for hepatitis C, such as Solvadi, Harvoni, and Viekira Pak, suggests the daunting challenge that lies ahead for payers as new, very expensive specialty drugs are brought to market for conditions affecting potentially large patient populations. Some of these drugs will be indicated for chronic conditions for which treatment may be lifelong, driving up costs in ways that cannot be predicted. The announcement last year of a new class of drugs to lower cholesterol for people who cannot tolerate statins (PCSK9 inhibitors), priced in the range of $15,000 per year, suggests the magnitude of the problem confronting not just Medicare Part B but Part D (these are self-injected) and commercial coverage.

Indirect Effects on Medicare Advantage

As encouraged as ACHP is with CMS' efforts to address the Part B drug cost issue, we also want to take the opportunity to provide insights that address specific aspects of the proposal. We urge CMS to carefully consider unintended consequences that may affect Medicare Advantage (MA) plans. Although the proposed demonstration does not directly address how MA plans and their enrollees pay for Part B drugs, the changes in the ASP payment methodology would likely produce spillover effects including on MA plan negotiations with prescription drug manufacturers and with contracting providers. In addition,

to the extent that the proposed demonstration may not be budget neutral over its five-year duration, it would affect the MA benchmarks against which our plans bid. Moreover, for more highly integrated health care systems, the provider side of some ACHP member plans would be directly affected by both the proposed demonstration's phase I and II provisions. More specific details follow.

Phase I of the Proposed Model

CMS proposes to test a new payment methodology for physician administered drugs covered under Medicare Part B which would replace the current statutory payment rate[1] based on ASP plus a 6 percent add-on fee with a payment rate equal to ASP plus a 2.5 percent add-on plus a flat fee of $16.80. The flat fee is added to maintain budget neutrality across the Medicare Physician Fee Schedule and the Outpatient Prospective Payment System (OPPS). (Drugs paid separately under the OPPS are also included in the model.) Part B covered drugs are also subject to the budget sequester effective April 1, 2013 through 2014. The sequester reduces payments that providers receive for Part B covered drugs by 1.6 percent,[2] which results in a net payment equivalent reduction from ASP plus 6 percent to ASP plus 4.3 percent. CMS proposes to require all providers and suppliers to participate in the model located in a geographic area (determined by Primary Care Service Areas (PCSAs)) that are chosen for participation. Approximately half of the United States is included in Phase I.[3] CMS proposes to include most Part B drugs in the model.[4]

Potential cost and site shifting. The Phase I provisions could introduce difficult challenges in plan negotiations with manufacturers and physicians. In some cases, our MA/PD plans have negotiated reimbursement with their contracted providers that is less than the ASP + 6 percent payment. They worry that, particularly for low cost drugs, providers receiving Part B payments under the new payment formula would bring pressure on them to raise these currently lower fees. A related concern is that providers receiving lower reimbursement on the Part B side will try to make up lost revenue by prescribing more expensive drugs to their MA/PD patients.

Questions arise also about the potential for the proposed Part B payment changes to encourage site shifting of care from physician offices to outpatient hospital settings. The fact that ASP is the average price means that some providers (and health plans) are paying more than ASP, some are paying less. Price negotiations with manufacturers are likely to be affected by the volume of drugs purchased by the provider or plan. Those with less purchasing clout may pay above average prices for drugs. Given that these provider groups already have to absorb the effects of sequestration, the payment changes called for by phase I of the proposed model may force them to re-evaluate how they continue to practice. It is not unreasonable to anticipate that some would refer patients to other providers (shifting many to outpatient hospital departments, for example) and some may decline to accept Medicare patients, outcomes which would create disruptions in care and potential access problems. We urge CMS to monitor for this potential effect to ensure beneficiaries are receiving timely and appropriate care.

---

[1] Section 1847A of the Social Security Act
[2] The 2 percent across-the-board reduction in Medicare payment does not apply to the 20 percent coinsurance or the deductible. Thus, the effective reduction on Part B drugs payments with respect to sequestration is about 1.6 percent (2.0*.8)
[3] CMS proposes to exclude Maryland (which is subject to a separate payment demonstration), American Samoa, Guam and the US Virgin Islands.
[4] CMS proposes to exclude vaccines, infused drugs administered through durable medical equipment, contractor-priced drugs, blood and blood products, and drugs included in the ESRD bundle.

"Brown Bagging." Another concern is that the proposed ASP payment change could encourage more "brown bagging" of drugs under Medicare Part B and Medicare Part D. As CMS is aware, some physicians give beneficiaries a prescription to obtain their Part B drug at a pharmacy. The patient must then bring the drug to the physician's office for administration. This practice is not good for the beneficiary due to product integrity and patient safety concerns, and would be an unfortunate unintended consequence of the demonstration. As CMS moves forward with the demonstration, ACHP recommends that it develop criteria to avoid increased use of brown bagging and provide for careful monitoring of this trend.

Availability of Alternative Drugs. ACHP supports CMS' efforts to reduce existing drug payment incentives that may favor the use of higher cost drugs over lower cost alternatives of equal efficacy. We suggest that, in moving forward with the proposal, CMS carefully consider those medical conditions for which a lower cost and equally effective alternative may not be available. It may be necessary to restructure the payment proposal, or build in an exceptions process, for those situations in which there is not an alternative. In addition, with reduced reimbursement, the costs associated with acquiring and keeping an inventory of higher priced drugs may be a disincentive for some providers. CMS should monitor for potential beneficiary access problems.

An additional potential effect on beneficiaries is that, to the extent that the proposed payment change increases reimbursement for specific drugs from what is currently paid, they will pay more than previously for Part B drug coinsurance. Although many beneficiaries have supplemental coverage, those who do not may be the least likely to afford the added out-of-pocket costs.

One alternative to calculating the ASP percentage add-on and flat fee that may mitigate these inappropriate incentives would be to use tiered reimbursement. For example, CMS could adopt tiered flat-fee add-ons or percentage add-ons (or a combination) based on the ASP for the drug. Lower cost drugs could be assigned a lower flat fee than the proposed $16.80; higher cost drugs could be grouped into tiers linked to higher flat fees. CMS considered this kind of tiered structure and rejected it, but we believe the option should stay on the table as CMS considers comments and potential changes to the proposed rule.

In addition to the issues discussed above on phase I of the model, we also want to express support for CMS' decision to exclude drugs infused with a covered item of durable medical equipment (DME) in the first year of phase I of the model. This one-year exclusion gives CMS an opportunity to assess whether it is appropriate to include DME as the model proceeds, taking into account the effects of doing so on beneficiary access.

Phase II Model Provisions

In phase II of the model, CMS proposes to implement value-based purchasing (VBP) tools for Part B drugs using strategies developed by health plans and other entities to manage health benefits. CMS sees VBP as linking payment for a drug to patient outcomes and cost-effectiveness, rather than solely to the volume of sales as is currently the case. CMS proposes to consider several VBP tools or strategies as well as a clinical decision support (CDS) tool for appropriate drug use and safe prescribing that would provide education and data on the use of certain Part B drugs to prescribers. The VBP tools would include one or more of the following: reference pricing, indications-based pricing, outcomes-based risk sharing agreements, and discounting or eliminating patient coinsurance amount.

ACHP strongly supports effective value-based strategies that reward high quality care and better patient outcomes. Our members have been leaders in implementing innovative strategies in their public and commercial products. ACHP agrees with CMS that some VBP tools, when appropriately structured, may

be adaptable to Part B to improve patient care and manage drug spending. The key to success is to identify those tools with a sound evidence basis that will improve the effectiveness, safety, and quality of physician prescribing patterns for Part B drugs.
ACHP supports the overall approach of testing VBP tools for Part B drugs. Our member plans have adopted some of these tools to manage their prescription drug benefits and have offered a number of observations. As CMS moves forward, it will be especially important to achieve a consensus among stakeholders on key criteria that will be used to establish when a drug or drug class is determined to be of greater value than another one. Patient perspectives must be part of the discussion on relative value. ACHP recommends that CMS use notice and comment rule-making rather than a subregulatory process for obtaining stakeholder comment. The regulatory process increases transparency and opportunity for public discussion and consensus-building about the VBP approaches.

Indication-based pricing. Indication-based pricing, by which CMS means varying prices of a given drug based on its varying clinical effectiveness for different indications covered under Medicare authority, has good potential to drive value-based medication use. Risk to beneficiary access, however, should be a consideration, especially if specific medications are reimbursed below cost. In this scenario, a beneficiary may have already tried and failed or developed toxicities to first-line, value-based medications – leaving alternative drugs which are second or third-line choices as the only available options for a given indication. Therefore, consideration must be given to the absolute differences in reimbursement relative to ASP among the drugs for a given indication. In addition, drugs not included in this type of payment strategy should maintain a "basic" reimbursement. The reimbursement should be lower than for an otherwise higher priced reimbursed drug so as to ensure that proper drug selection is supported financially. Otherwise, drugs which are used off-label for a given indication may be prescribed more liberally if they are not otherwise delineated in an indication-specific treatment listing.

Indication-based pricing, if not implemented carefully, may have the unintended effect of influencing the manner in which manufacturers of brand drugs and biologics determine which indications they seek for FDA approval. For example, if the manufacturer of a specialty drug requests and obtains FDA approval of the drug for conditions x, y, and z and a biosimilar has marshalled the necessary evidence for FDA approval for condition x, would providers be discouraged financially or by policy from using the biosimilar for conditions y and z? These types of subtle but potentially important effects should be weighed in determining the appropriate Part B drugs that are included in indication-based pricing.

Discounting or eliminating patient coinsurance amounts. Encouraging the use of high value Part B drugs by eliminating or reducing patient coinsurance amounts can be an effective patient-focused strategy. We recommend that it be connected to the indication-based pricing strategy such that a particular drug's coinsurance is reduced or eliminated for indications of disease x and disease y but not for disease z if the clinical evidence demonstrates differences in patient outcomes and/or value relative to other medications used across the various disease states mentioned.

Part B drugs which lend themselves to value-based pricing in the context of indication-specific pricing and/or co-insurance reduction include, but are not limited to: anti-rheumatologic agents (ex., drugs for rheumatoid arthritis, psoriasis), biologics used in Crohn's disease and ulcerative colitis, botulinum toxins, ophthalmologic conditions, anti-emetics used with chemotherapy regimens, intravenous immune globulins, colony-stimulating factors, anti-neoplastic/chemotherapeutic drugs used in specific cancer diagnoses, and infused drugs for multiple sclerosis. Submission of the appropriate disease diagnosis codes concurrently with the drug codes would be required for the appropriate value-based pricing to be applied.

Outcomes-based risk sharing agreements. Under this approach, CMS would enter into voluntary agreements with manufacturers to link health care outcomes with payment. The final price of a drug would thus be tied to results achieved by specific patients and not tied to a predetermined price based on historical population data.

Using rebates, refunds or price adjustments if the drug does not achieve targeted outcomes could be a promising approach. It entails a certain degree of complexity and risks, however. Importantly, eligible outcomes need to be clinically relevant; use of surrogate markers alone and/or "statistically significant" changes must be linearly tied to clinically meaningful outcomes. Providing for rebates or refunds would likely encourage use of a particular drug. If such an arrangement is not also tied back to evidence-based medicine with respect to relevant differences among agents within a category of drugs, drugs with less robust data could be prescribed ahead of those supported by better overall evidence.

If CMS adopts this tool as part of the VBP portion of the demonstration, we recommend that it require that a proportion of the manufacturer rebate be returned to the ultimate payer(s) – in the Medicare FFS program, the federal government and the beneficiary. In addition, all rebates should still be utilized to calculate ASP. If excluded, then the ASP would not represent a true average sales price, fueling drug price inflation by manufacturers who would then incentivize providers with large rebate opportunities so that they could obtain margin over their acquisition costs. This scenario is what led Medicare to develop the ASP reimbursement method in the first place.

Clinical Decision Support (CDS) Tool. CMS is considering including in Phase II a CDS tool to support accurate evidence-based prescribing. This would be along the lines, for example, of a tool providing clinical information to the prescriber at the point of care on a patient–specific basis in real time to help the prescriber identify potential problems and provide suggestions to support the clinical decision. The CDS would consist of an on-line tool that provided education and then feedback based on drug utilization reported in Medicare claims. CMS would develop the tool; its use by prescribers participating in the VBP part of the demonstration would be voluntary.

ACHP supports this proposal and offers several recommendations. A number of ACHP member plans have implemented value-based advanced physician payment models for some or all of their lines of business. They are designed to reduce the total cost of care and improve health by rewarding providers for quality and specific health outcomes, such as improved management of diabetes or high blood pressure. Some employ shared financial risk with plan network physicians; others expect to move in that direction but have begun with pay-for-performance. For these alternative payment models to successfully drive improvement, health plans need to develop actionable performance data, include patient satisfaction and clinical outcomes measures, and initiate frequent payer-provider engagement at the individual clinician level. This last point is particularly salient with respect to the potential employment of CDS tools to influence providers' drug prescribing behavior.

If CMS moves forward with the Part B drug Payment Model to include an on-line CDS and feedback component, it will be important to take into account such variables as the willingness of the local provider community to participate; the potential need and expense of adding to or changing their information technology infrastructure; and the resources needed to educate and maintain physician engagement. Additional considerations should include best practices for providing constructive feedback and support to physicians.

Further Considerations

ACHP recommends that CMS build into both phases of the Part B Drug Payment Model more explicit beneficiary access and quality safeguards. Although we appreciate the proposal to include a pre-appeals

exceptions process, it will be critical for CMS to monitor manufacturer and provider responses to the different aspects of the demonstration, to ensure that beneficiaries receive appropriate and timely access to prescribed medications. Monitoring should include changes in prescribing patterns that indicate possible under- as well as over-treatment.

We urge CMS to provide greater specificity in its final rule on the nature of the demonstration evaluation – for example, how CMS plans to assess improvements in the quality of care. We believe it is also important to provide for routine public reporting as implementation of the demonstration proceeds, including changes in Part B drug costs, utilization of Part B drugs, health care outcomes, shifts to more expensive sites of care, and beneficiary, provider and supplier experience.

Thank you for your consideration of ACHP's comments. Again, we support CMS' efforts to address the rising costs of Part B drugs, and we welcome the opportunity to work with the agency to avoid unintended consequences and reward appropriate prescribing. If we can answer any questions or provide additional information, please contact Howard Shapiro, Director of Public Policy, at hshapiro@achp.org.

Sincerely,

Ceci Connolly
President and CEO