May 9, 2016

Andrew M. Slavitt  
Acting Administrator  

Attention: CMS-1670-P  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

RE: CMS-1670-P; Medicare Program; Part B Drug Payment Model. Submitted electronically via http://www.regulations.gov

Dear Acting Administrator Slavitt,

Trinity Health appreciates the opportunity to comment on the proposed policy and payment changes set forth in CMS-1670-P. Our comments and recommendations to the Centers for Medicare and Medicaid Services (CMS) reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 21 states. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 90 hospitals, 120 continuing care programs — including PACE, senior living facilities and home care and hospice services that provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns about $1 billion to our communities annually in the form of charity care and other community benefit programs. We have 31 teaching hospitals with Graduate Medical Education (GME) programs providing training for 1,951 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 95,000 full-time employees, including 3,900 employed physicians, and have almost 13,800 physicians and advanced practice professionals committed to 19 Clinically Integrated Networks across the country.

Trinity Health is an organization that is committed to rapid, measureable movement toward value in the delivery of and payment for health care. We wholeheartedly support Secretary Burwell’s announcement of tying 30 percent of traditional—or fee-for-service Medicare payments—to quality or value through alternative payment models by the end of 2016; and tying 50 percent of payments to these models by the end of 2018. In fact, Trinity Health has committed to having 75 percent of our revenue in value-based arrangements by 2020 as a member of the Health Care Transformation Task Force.

We appreciate CMS’ ongoing efforts to improve payment systems across the delivery system. If you have any questions about our comments, please contact me at wellstk@trinity-health.org or 734-343-0824.

Sincerely,

Tonya K. Wells  
Vice President, Public Policy & Federal Advocacy  
Trinity Health
Trinity Health Supports Efforts to Address the Rising Cost of Drugs, but has Some Concerns with CMS’ Proposed Approach Under Phase I

CMS proposes the Part B Drug Payment Model as a two-phase model that would test whether alternative drug payment designs will lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. The first phase involves revising the current payment methodology for Part B separately payable drugs. In the second phase, CMS would implement value-based purchasing (VBP) tools similar to those employed by commercial health plans, pharmacy benefit managers and other entities that manage health benefits and drug utilization.

We share many of the agency’s concerns over the rising cost of drugs, and specifically with the growth in Medicare spending under Part B of the program for separately payable drugs. Trinity Health applauds the agency’s attention to this problem, and its continued efforts and initiatives to address the financial stability of the Medicare program as well as the persistent dedication to protecting and enhancing the quality of care provided to Medicare beneficiaries. CMS reports in the Proposed Rule that Medicare spending for separately payable drugs in the hospital outpatient department setting more than doubled between 2007 and 2015, from $3 billion to $8 billion respectively. As a large, mission-driven, multi-state health system serving a diverse socioeconomic population, we are all too well aware of the challenges facing Medicare beneficiaries and health care providers by sustained year-over-year growth in drug spending. Our most recent data indicates that Trinity Health experienced an 11 percent growth in overall drug costs from 2014 to 2015. As such, we share CMS’ desire to find a comprehensive solution. We likewise share the agency’s belief that evidence-based policies that encourage cost-effective, high-quality care will help bring about the important changes that will address rising costs and enhance quality of care. Nonetheless, while Trinity Health supports the intent of the proposed rule, we have many concerns with the current proposal.

In most cases, Medicare pays for drugs that are administered in a physician’s office or the hospital outpatient department at Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on which is then reduced to 4.3 percent under the budget sequester enacted in 2011. In Phase I of the two-phase model, the agency proposes to implement an alternative to the add-on component of the Part B payment methodology in different geographic areas of the country. Under the proposal, CMS would retain the current rates in some communities and set a reduced rate of ASP+2.5 percent in addition to a $16.80 flat fee in others. After sequestration is factored in, the add-on in the demo areas would be 0.86 percent of ASP plus $16.53. In our review of the proposal we identified several significant problems that we believe may negatively impact the Medicare program, providers and beneficiaries.

The proposed ASP methodology will not cover acquisition costs, let alone handling costs: Trinity Health is very concerned that the proposed reimbursement rates will not adequately cover the acquisition cost of many drugs subject to this program. Often, even the current methodology does not cover true costs because the ASP rate includes payments that were heavily discounted to reflect volume, prompt pay and other such adjustments. Trinity Health has found that we are not always able to benefit from these discounts, and that our acquisition costs can be greater than ASP. This situation is exacerbated because ASP rates are based on data from at least six months ago and drug prices are rising at a faster rate making it difficult for Medicare reimbursement rates to keep up with the actual acquisition costs facing providers. While CMS regards the 6 percent add-on as intended to cover the cost of handling, in reality it frequently closes the gap between acquisition costs and the reimbursement amount. The proposed reductions will be inadequate to cover this difference for more expensive drugs. Trinity Health is concerned that a reduction in the current payment rate for these more expensive drugs could compromise our ability to offer certain therapies, which could compromise beneficiary access and health.

When Trinity Health analyzed the top 20 most commonly used drugs in the Medicare hospital outpatient setting covered under Part B, we learned that the current level of reimbursement of ASP + 6% does not cover our acquisition costs for seven of these high volume drugs. In most cases, the magnitude of the loss per patient treatment is significant; in some cases near $1,000/case. This is before the proposed reduction to ASP + 2.5% plus flat fee.

We also find it difficult to support this proposal given that CMS has not provided an evidence-based rationale for the proposed alternative payment methodology in Phase I. Before CMS moves forward with such a significant change in policy, more information needs to be provided on how this methodology was developed and why it is more
appropriate than the current methodology or any alternatives. For example, CMS has not explained why the approach it is proposing is, in fact, likely to save costs while maintaining or improving quality of care.

Additionally, CMS has not set forth a plan to evaluate the demonstration with specific outcome measures, timelines for analysis and methods of analysis, all of which are basic standards for good research practices. Absent an evaluation component, it is not clear that CMS will have the relevant and necessary information needed to determine the success of the program or identify components of the program that need to be modified or altogether abandoned.

**The proposal does not address the true problem of rising drug costs:** Through this proposal CMS is attempting to address the growth in Medicare spending on separately payable drugs by adjusting the rate it reimburses hospitals and physicians for these products. Although the rate of spending in Part B for separately payable drugs and biologicals has increased, CMS has not provided evidence that the reason for such growth is the ASP+6 percent payment methodology, or a result of the providers that furnish these therapies. From our perspective, this growth is driven by increases in drug costs. Yet CMS is choosing to target—not the entities setting drug prices—but rather the purchasers who have no control over prices.

**The proposal would redistribute reimbursement among providers for no apparent reason and with no obvious benefit:** Although Phase I is budget neutral, this mandatory program will have a significant impact on providers and patients across the country because it will redistribute payments across provider types and among specialties, and it does so without providing a clear rationale. First, the proposal penalizes hospitals because it shifts money from hospitals to physicians. The proposal also penalizes some specialties of physicians because it shifts money to primary care physicians. The overall effect will be to shift money from hospitals and specialties that use higher-cost drugs, to specialties that use lower-cost drugs. CMS estimates that under the alternate drug payment model in Phase I, hospitals will see a decline of 2.3 percent in Part B drug payments, an estimated overall cut to hospital spending of about 0.3 percent. While the end result of this revised ASP methodology will be to ratchet down the payment for some drugs and increase the payment for other drugs, it is unclear how this new redistribution achieves CMS' objectives.

**The proposal threatens access to important therapies:** If nothing else, Medicare’s current payment policy of ASP + 6 percent facilitates beneficiary access to drug therapies. Trinity Health believes any modification to the current program to address cost concerns should be balanced with protecting access. Trinity Health is concerned this proposal may threaten patient access to certain drugs, and access to care in certain settings.

For example, we are concerned that this proposal could be particularly challenging for Trinity Health’s rural facilities. In the Proposed Rule, CMS indicates that rural hospitals are estimated to experience smaller reductions than urban hospitals. While we appreciate the agency’s efforts to isolate the impact on rural hospitals, we are concerned that this analysis did not fully consider the circumstances of rural hospitals and their sensitivity to payment reductions. These providers often have higher shipping costs, which make them particularly vulnerable to lowered reimbursements. Further, our rural providers—like most rural providers across the country—tend to have a higher proportion of Medicare beneficiaries, which leaves them less able to offset inadequate Medicare payments among other patients. Moreover, volume of services in these settings can be lower, which means the per-unit-cost of each product typically is higher. In many of these communities, the Trinity Health hospital is the sole provider of certain medications and services. As a mission-driven system, we are committed to meeting the needs of our patients. Trinity Health will continue to provide access to these treatments to our patients, but the result of such a policy will be to shift the burden of absorbing these uncompensated costs to providers like Trinity Health and other mission-driven institutions committed to maintaining access to care to underserved and hard to reach populations. We urge CMS to more completely study the impact of this proposal on Medicare beneficiaries in rural areas before implementing such wide-ranging and significant changes.

We are also very concerned about the disproportionate impact this proposal could have on oncology services. A June 2015 report by the Medicare Payment Advisory Commission (MedPAC) identified the top ten Part B-covered drugs according to total expenditures. Seven of the top ten drugs were for patients with a cancer diagnosis. Cancer patients can be especially vulnerable because they may not have the luxury of choosing a less expensive option because one does not exist; they have tried the other options and these were either not effective or the side effects were too debilitating to continue with the treatment.
There is a lack of evidence that the current payment methodology inappropriately incentivizes providers:

Trinity Health understands that the 6 percent add-on has been criticized by policymakers as incentivizing the prescription of high-cost drugs, as they provide a higher add-on payment for the physician or hospital administering the drug.

Trinity does not believe that there is sufficient evidence to support these conclusions. In many instances the medical provider has a single choice in choosing a drug, or drug selection is based on a trial and error process of finding the drug that is most effective for the patient and their unique condition. In these circumstances, clinical considerations—not financial concerns—are driving product selection.

A more effective means of addressing this issue would be to promote policies and develop tools that make it easier for providers to make evidence-based decisions. For example, Trinity Health supports the proposal described as part of Phase II VBP tools to develop on-line evidence-based clinical decision support tools. This type of resource could support the safe and appropriate use for selected drugs and indications.

CMS has proposed an inappropriately ambitious and aggressive implementation timeline: Trinity Health believes that the scope and breadth of the proposal are well beyond a true demonstration program, but rather reflect a wholesale replacement of the statutory payment framework with an administratively imposed framework. Yet, despite the large task facing CMS, they do not seem to have allotted sufficient time to implement this important program. Payment changes will potentially occur by the end of 2016—in a few short months. Based on the timeline in the Proposed Rule, these payment changes will be swift and abrupt. Many providers will struggle to absorb these losses and adjust to the new reimbursement rates.

For these reasons, Trinity Health is concerned by the ambitious implementation timeline outlined in the Proposed Rule. Providers will have considerable trouble adjusting to the abrupt and mandatory shift in payment policy before the end of 2016, and then to the expanded program next year with up to five additional drug payment modifications that are yet to be described in any detail. These changes will also be occurring simultaneously with the implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. As a health system that employs 3,900 physicians, we are also bracing for the many changes that will be required to comply with MACRA beginning in 2017.

Trinity Health strongly urges CMS not to finalize Phase I. If CMS chooses to move forward with Phase I in the expedited manner outlined in the proposed rule, Trinity Health encourages the agency to move forward with this proposal on a more limited basis. For example, CMS could limit the drugs to which this proposal would apply. In many instances, there may be only one drug available to treat a specific condition. Sometimes even when there are multiple options available in general, for a specific patient there may be only one safe and effective option. If CMS chooses to test ASP add on changes, it should only apply in those instances where there is more than one class of drugs with equivalent efficacy and safety options. Otherwise, there is nothing to test. There is no incentive for the clinician to choose the more expensive drug—because there is only one drug from which to choose. CMS should work with pharmacy professionals to establish which classes or groups of drugs should be included in the demonstration and allow for substantial stakeholder feedback prior to finalizing the list.

If CMS chooses to include all drugs covered under Part B, we urge the agency to consider a tiered approach that would establish an add-on payment that is at least be proportional to the cost of the drug. Otherwise, in those instances where there is only one option for a critical condition and it is an expensive option, CMS will risk either reducing Medicare beneficiary access to important treatments or requiring providers to absorb the difference in costs, which at times can be very significant.

Additionally, if CMS chooses to move forward with Phase I, we believe it would be more appropriate to initially implement this as a demonstration project limited to a small, defined geographic region, or to a selected number of randomly selected regions across the country.

Even with a more clinically-focused and geographically-limited approach, we believe it would be appropriate to exclude some hospitals, practices and individual clinicians from Phase I of the model. Specifically, we recommend excluding clinicians and organizations who participate in the Oncology Care Model, shared savings programs and other alternative payment models (APMs). Significant effort has gone into the design and development of these
models. Any attempt to introduce wholly-independent elements into these programs without consideration of the larger APM that is being tested could be harmful to the APM as well as the Part B model. In addition to any unintended consequences, it would be difficult to disentangle the cause of any observed changes in drug utilization or clinician prescribing behavior.

**Trinity Health Recommends that CMS Pair the Value-based Tools Proposed in Phase II with Other Value-based Purchasing Initiatives**

In Phase II, which could be implemented as soon as January 2017, CMS would apply VBP tools similar to those employed by commercial health plans, pharmacy benefit managers and other entities that manage health benefits and drug utilization in conjunction with the Phase I variation of the ASP add-on payment amount for drugs paid under Part B. The proposed VBP strategies include: reference pricing, indications-based pricing, risk-sharing agreements based on outcomes, discounting or eliminating patient cost-sharing, and feedback on prescribing patterns and online decision support tools.

Over the years, Trinity Health has strongly embraced efforts by the agency to transition Medicare from a fee-for-service, volume driven system to one based on evidence-based, clinical decision making that supports high quality, cost-effective care. This commitment is demonstrated by our leadership in developing accountable care organizations and with the Health Care Transformation Task Force. Nevertheless, Trinity Health has numerous concerns with the proposals in Phase II.

**CMS provides insufficient details in Proposed Rule for Trinity Health or other stakeholders to comment:**

CMS gives only passing reference to some of the tools under consideration, and makes no concrete proposals as to which tools it would deploy, and how it would choose to do so. Instead, CMS says that it will leave that tool selection to the Final Rule, and that it will then describe how the tools will be deployed. CMS indicated in the Proposed Rule that after the Final Rule is released these tools would be implemented through subregulatory guidance. Trinity Health is alarmed by this approach. Limited information is provided regarding the VBP tools themselves, the experience of other payors with these tools or how CMS plans on developing and introducing them into the Medicare environment. CMS’ descriptions and details in the Proposed Rule are not sufficiently defined, and without greater detail, we cannot effectively comment on CMS’ proposals. Moreover, passing up the opportunity for a vibrant Proposed Rule comment process by withholding details until the Final Rule is published seems to violate the purpose of the public comment process. We strongly believe that the widespread implementation of such complex VBP tools requires their own, separate Proposed and Final regulations’ process.

CMS states in the proposed rule: “We do not believe that we have enough detail on the structure of the final VBP component to quantify potential savings at this time.” CMS also acknowledges the potential risk of these tools: “We are mindful that, in particular circumstances, the arrangements discussed here, if not properly structured and operated, could pose a risk of abuse.” CMS needs to better understand its own proposals and their consequences before it makes such proposals. Moreover, the affected community needs a genuine opportunity to evaluate and comment before such changes should be made, and we can do that only with concrete proposals and sufficient evidence and modeling by CMS.

Trinity Health envisions that the introduction of VBP tools in the Part B drug environment will also entail not just the initial implementation of these tools, but – as new studies are published and treatment protocols are revised – these tools will need regular updates. In fact, ongoing maintenance of these tools will likely be required. Just as CMS has a detailed and thorough strategy to update and maintain their stable of quality measures, similar efforts will need to be deployed around the maintenance of these VBP tools to ensure that they continue to be effective and are based on the most current evidence. Because of the pace of new studies being published on drug treatments, in many ways the drug space is more dynamic and will require even more maintenance than quality measures. Yet, the proposed rule did not provide any details on this issue. Trinity Health believes that a plan for the ongoing maintenance of the VBP tools is a critical component of any proposal related to the introduction of VBP tools in the Part B drug space.

Most importantly, CMS’ proposals need to comport with the clinical reality of patient care. Inherent in several of the Phase II proposed tools (e.g., reference pricing, indication-based pricing, reduction of cost-sharing) is the assumption that treatment alternatives within Part B are clinically equivalent – i.e., for any particular drug or
biological therapy there are alternative and substitutes that can achieve the same clinical outcomes. In reality, there are no alternatives for many drugs and biologicals covered under Part B. This reality alone could severely limit the agency’s ability to successfully implement these tools, to achieve its goals and to insulate beneficiaries from harm.

**CMS provides insufficient clarity on the timing of implementation:** We are also very concerned by the lack of clarity on the timing of the implementation of these tools. Individually these are very complex programs with which both CMS and providers have very limited experience. The application of these tools may vary by geographic location or by product. Hospitals will need time to prepare for these programs. It is insufficient for CMS to indicate in the proposed rule that it will implement these changes at some point after January 2017. That could be as soon as eight months from now. CMS needs to first give providers more details about the program, and then provide ample time to prepare for the changes before CMS implements any new policies of this significance.

In our comments on Phase I above, we raised similar concerns about the ambitious timeline. These concerns also apply to Phase II. It is wholly inadequate to provide 45 days notice prior to the implementation of a VBP tool as CMS indicates it might provide. The complexity of the tools that are being discussed here, and the prospect that providers may have to work with multiple tools simultaneously suggests that CMS must give well more than 45 days.

**The proposal is inconsistent with how CMS has been implementing VBP tools in other sectors of the Medicare program.** In recent years, through the development and implementation of numerous APMs including bundled payment initiatives, the Center for Medicare and Medicaid Innovation (Innovation Center) has developed considerable experience in promoting value-based care. Unlike these other initiatives, the Part B Drug Model is not focused on a population or an episode of care, but rather is simply focused on the price and utilization of discrete products.

This approach is both too broad (by collapsing all conditions into one model) and too narrow (by focusing on drug utilization in isolation). For this reason, this approach will prove to be not only ineffective because it will not address the true problem of the rising cost of drugs, but also dangerous because it could risk Medicare beneficiary access to important and necessary treatments. Consequently, we strongly discourage CMS from implementing these VBP tools on their own. Instead, CMS should explore how these tools can be integrated into larger VBP efforts.

**CMS should consider allowing providers to opt for a single VBP tool.** Systems, such as Trinity Health are able to embrace aggressive transformation goals because of size, scale and sophistication. However, CMS can undermine those capabilities and compromise our ability to truly test models as well as our ability to succeed if it strives to apply different models to different providers based on geographic location. Because of Trinity Health’s expansive footprint, it is conceivable that we could be required to test several models at once, when it would be far better to allow a system, such as Trinity Health, to test a single model across its many providers. Trinity Health urges CMS to allow providers to opt for a single VBP tool.

**CMS has other options to spur innovation.** We understand that CMS is trying to spur innovation in Part B drug spending by reducing costs, maintaining access and enhancing quality. As a first step in that direction, Trinity Health urges CMS to consider increasing the Part B drug purchasing options available to providers. We believe such efforts could have significantly positive effects on Part B drug spending and quality of care. Trinity Health recommends that CMS put forth a clear pathway for providers, especially those engaged in APMs, to contract directly with manufacturers for developing outcomes based pricing, “try before you buy” rebate arrangements, and episode of care payment.