May 9, 2016

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1670-P
P.O. Box 8016
Baltimore, MD 21244-8016

BY ELECTRONIC DELIVERY at http://www.regulations.gov

Re: Submission of Comments Pursuant to CMS-1670-P – Proposed Rule: Medicare Program; Part B Drug Payment Model (RIN: 0938-AS85)

Dear Acting Administrator Slavitt,

Astellas Pharma US, Inc. (“Astellas”) appreciates the opportunity to submit comments regarding the proposed rule entitled Medicare Program; Part B Drug Payment Model (the “Proposed Rule”) that was recently issued by the Centers for Medicare and Medicaid Services (“CMS” or “the Agency”).

Astellas is an innovator company and our fundamental goal is to improve the health of individuals by developing and marketing safe and reliable treatments that address unmet medical needs in the therapeutic areas of oncology, urology, cardiology, infectious disease, and immunology. We are also focusing research investment efforts in unmet areas of muscle disease, ophthalmology, regenerative medicine and vaccines. Astellas writes today to join the many patients, providers and other stakeholders calling for CMS to withdraw the Proposed Rule.

Indeed, we share the view of many stakeholders in the patient and provider communities that the Agency does not have the authority to implement the proposal. Even more fundamentally, however, Astellas shares the concerns already expressed by other stakeholders that the unintended consequences of the Proposed Rule, if implemented, will inevitably be to threaten access to important therapies for Medicare beneficiaries, increase prices, and deter the innovation that is so desperately needed to address unmet needs. Further, we believe that significant ethical questions are raised by the Proposed Rule as patients’ ability to access much needed drugs will be limited. We also express a number of concerns regarding the lack of stakeholder involvement in the process that led to the development of the Proposed Rule and the manner in which it was announced.

Astellas shares the Agency’s commitment to advancing the health of Medicare beneficiaries; further, Astellas supports the Agency’s goal of promoting the sustainability of the Medicare program. This effort to promote sustainability, however, should not come at the expense of beneficiaries’ access to the most appropriate clinical therapy to meet their needs. Astellas is not alone in voicing these serious concerns about the Proposed Rule; more than 300 provider

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organizations, patient advocacy groups, industry trade associations, and other manufacturers are among the stakeholders that have expressed concerns about the negative unintended consequences that will result from the Proposed Rule, if finalized. Many of these stakeholders have also questioned the authority cited by the Agency for its proposal.

In our comments below, we first explore, as a threshold matter, how the Proposed Rule is inconsistent with the underlying statute and does not meet the statute’s procedural requirements. In this section, we also discuss the ethical issues that are a source of concern to us and to other stakeholders—and that explain the basis for the procedural safeguards in the authorizing statute that would not be met under the Proposed Rule. We then discuss the negative effects that we and so many other stakeholders anticipate resulting from the Phase 1 and Phase 2 proposals, in the form of reduced access to reasonable and necessary treatments, higher prices, and decreased innovation. For these reasons, we urge CMS to withdraw the Proposed Rule.

Throughout this letter, we utilize the naming convention “Phase I” and “Phase II” to refer to the requirements outlined in the statute, and “Phase 1” and “Phase 2” when discussing the phases of the models in the Proposed Rule.

I. The Proposed Rule Is Inconsistent with the Underlying Statute and Exceeds CMS’ Authority Under 42 U.S.C. § 1315A.

The Proposed Rule, if implemented, would exceed the authority CMS was granted. An administrative agency is a “creature of statute,” and “any power or authority claimed by it must find its source within the provisions of the statute by which it is created.” CMS may only exercise the powers expressly delegated to it by Congress because “[w]hen Congress passes an Act empowering administrative agencies to carry on governmental activities, the power of those agencies is circumscribed by the authority granted.”

CMS cites Section 1115A of the Social Security Act (“SSA”) as the source of its authority to waive standard Medicare payment rates for Part B drugs and implement the proposed nationwide payment change for virtually all Part B drugs, notwithstanding the very different reimbursement rates and systems mandated elsewhere by Congress for Part B drugs. Under the statute, Congress created the Center for Medicare and Medicaid Innovation (“CMMI”) “to test

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3 Letter from industry groups to Andy Slavitt, supra note 2.


6 Importantly, a federal court has held that another attempt by the Agency to deviate from the SSA was invalid under the SSA and the Administrative Procedure Act. See Hays v. Sebelius, No. 08-5508, 2009 WL 4912383 (D.C. Cir. 2009).
innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care furnished to individuals.”7 The statute further instructs that the models should target “a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.”8 And the statute gives context to these scope of authority restrictions by directing that preference should be given to “models that also improve the coordination, quality, and efficiency of health care services.”9

Various safeguards are an integral component of the statute. As an overarching matter, “in carrying out the duties under this section, the [CMMI] shall consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management.”10 This procedural protection is further underscored by the statement that “[CMMI] shall use open door forums or other mechanisms to seek input from interested parties.”11 Proposal and selection of a model are, of course, part of the “duties under this section.”12

One of the statute’s most important protections and limitations is that demonstrations, as authorized by the underlying law, can only proceed in two defined phases. Specific limitations are associated with both Phase I and Phase II demonstrations.

With respect to Phase I, the statute specifically states that the Secretary “shall” only “select . . . models in accordance with selection criteria under paragraph (2).”13 Subsection (2), again using mandatory language, states that the “selection of models to be tested . . . shall” involve models “where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.”14

Phase II has its own limitations and protections. Significantly, before proceeding to Phase II, a Phase I demonstration “shall” be subject to “an evaluation of each model tested,” the elements of which are specified by the statute.15 “Expansion of models (Phase II)” can only occur after “[t]aking into account the evaluation under section (b)(4),” the Phase I evaluation.16 Phase II expansion requires that the Secretary act “through rulemaking,” which itself must “tak[e] into account” the Phase I evaluation, demonstrating quite clearly that the Phase II rulemaking process can only occur after both Phase I and the mandated Phase I evaluation are completed.17 Further, Phase II can only occur in conjunction with various determinations by the Secretary and the Chief Actuary of CMS that also must “take[e] into account” the Phase I evaluation.18 Expansion

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7 42 U.S.C. § 1315a(a)(1).
8 42 U.S.C. § 1315a(b)(2).
11 Id.
12 Id.
14 42 U.S.C. § 1315a(b)(2).
16 42 U.S.C. § 1315a(c).
17 42 U.S.C. § 1315a(c).
18 42 U.S.C. § 1315a(c)(2).
is permitted, “including implementation on a nationwide basis,” only when the requirements of Phase II have been met, including the evaluation of “each model” proposed for expansion.\(^{19}\)

The proposed Phase 1 and Phase 2 models do not adequately satisfy the statutory requirements and the protections mandated by Congress. They are, thus, inconsistent with the authority granted to the Agency under the statute.

A. A Model Premised on a Reduction in the ASP Add-On Payment Is Not an Innovative Model.

CMMI is designed to test “innovative payment and service delivery models.”\(^{20}\) We believe Congress meant to give effect to the word “innovative,” particularly since the sponsoring Center is a center for “innovation.” According to Oxford dictionary, the word innovative means “featuring new methods” or “advanced and original.”\(^{21}\) CMS has not proposed a new, innovative model in Phase 1 for Part B drug payments but, rather, proposes to use the existing payment model and merely reduce the payment rate. Based on the plain meaning of the term “innovative,” reducing providers’ payments through the same reimbursement model is not new, advanced or original, and thus, not a valid exercise of the authority granted.

Further, providers administering Part B drugs are, in fact, currently already testing a very similar model to the Phase 1 proposal, as they have been facing payment reductions due to changes mandated by sequestration legislation since April 1, 2013.\(^{22}\) The statutory sequestration change reduced the payment that providers receive by 2%, such that providers are paid at 104.3% of the drug’s average sales price (“ASP”) rather than 106%. The Phase 1 proposal is not innovative because it only provides an additional reimbursement reduction on top of the reduction that has already been in place.

B. The Model Fails to Target a Defined Population.

CMMI is given authority for the specific and limited purpose of implementing targeted models that address a “defined population” with a defined need. In interpreting the statute and the authority granted under the statute, effect must be given to each word.\(^{23}\) The proposed Phase 1 model exceeds the statutory authority of the Agency, because it does not limit the proposal to a defined population.

Specifically, the Proposed Rule is not directed to a particular subset of Part B drugs, beneficiaries, or providers, but instead seeks to encompass virtually all Part B drugs, regardless of the condition or disease, the provider type administering the product, or the site of service. If Congress wanted CMMI to establish models that fundamentally impacted the system so broadly, it would not have specified that the models should address a “defined population” suffering from particular “deficits in care.” Moreover, if a Phase I model could encompass all or virtually all of

\(^{19}\) 42 U.S.C. § 1315a(b)(4).
\(^{21}\) Innovative, Oxford Online Dictionaries (2016).
\(^{23}\) Inhabitants of Montclair Tp. v. Ramsdell, 107 U.S. 147, 152 (1883) (“[i]t is the duty of the court to give effect, if possible, to every clause and word of a statute). See also Safeco Ins. Co. of America v. Burr, 127 S.Ct. 2201, 2210 (2007) (same); United States v. Menasche, 348 U.S. 528, 538 (1955) (same).
the Medicare Part B population, Congress would not have imposed a distinct set of requirements that must be satisfied before a test on a defined population was expanded through the Phase II process. As proposed, Phase 1 in effect skips to what is actually a Phase II model under the statute. However, as explained more fully below, this cannot be lawfully done without satisfying the requisite procedure.

Significantly, even other CMMI models, such as the Comprehensive Care for Joint Replacements (“CCJR”) model, which itself has been questioned in terms of its scope and whether that scope is consistent with the statute, identify a much more targeted population and a specific condition.24 Thus, the Agency has experience designing innovation models that are much more narrowly tailored to a potential care deficit impacting a specific subset of Medicare beneficiaries.

**C. A Five-Year Demonstration, Imposed on Virtually All Part B Drugs, Is Not a Test.**

The statute could not be clearer that the Agency’s demonstration authority is limited to effecting “tests” of new models. As defined by Oxford dictionary, to test means to “take measures to check the quality, performance, or reliability of (something), especially before putting it into widespread use or practice.”25

The proposed Phase 1 model’s national scope and its five-year duration are so widespread that it cannot be fairly understood as a test. Significantly, the Agency already has vast real world data available to it regarding the effect of reducing ASP percentage reimbursement rates.26 Rather than being a test, the Phase 1 proposal is a further reduction to an already established, widespread Medicare Part B reimbursement policy, undertaken without statutory authority and, in fact, contrary to the specific reimbursement standards created by Congress.

Leveraging CMMI’s ability to implement demonstrations to enact what are effectively reductions in statutory mandated reimbursement rates on a national, mandatory basis is beyond the authority granted to the Agency and CMMI.27 The statute was designed to facilitate small-scale pilot programs that may eventually be adopted on a wider basis, after a series of procedural safeguards (not satisfied here) have been met.

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24 The recently finalized CCJR model will be implemented in 67 areas covering approximately 800 hospitals. These 800 hospitals represent fewer than 15% of the total number of hospitals in the United States. Centers for Medicare and Medicaid Services, Comprehensive Care for Joint Replacement Model, *available at* https://innovation.cms.gov/initiatives/cjr (last accessed Apr. 18, 2016). Other CMMI models are considerably smaller. For instance, the Pioneer ACO model currently includes nine participating ACOs and the Comprehensive End-Stage Renal Disease (“ESRD”) Care model has partnered with a total of 13 organizations. Centers for Medicare and Medicaid Services, Pioneer ACO Model, *available at* https://innovation.cms.gov/initiatives/Pioneer-aco-model/ (last accessed Apr. 18, 2016) and Centers for Medicare and Medicaid Services, Comprehensive ESRD Care Model, *available at* https://innovation.cms.gov/initiatives/comprehensive-ESRD-care/ (last accessed Apr. 18, 2016).


26 Providers administering Part B drugs have been operating under reduced reimbursement rates due to sequestration budget cuts for over three years. As a result, CMS already has the data to examine whether a reduction in ASP rate influences providers’ prescribing habits. There is no need to test this concept, which, in any event, is not innovative. 27 *See* Peters v. Hobby, 349 U.S. 331, 345 (1955) (“[a]gencies . . . must of course be free to give reasonable scope to the terms conferring their authority. But they are not free to ignore plain limitations on that authority).
Not only does the Proposed Rule not introduce a valid test, we are concerned that it will compromise legitimate innovation models currently being tested by CMMI. The government, providers, manufacturers, policymakers, and patients are investing time and resources into other CMMI models that are already underway, such as the Pioneer ACO model. Part B drugs are not exempt from these other models, and providers’ prescribing behavior with respect to Part B will be influenced by the CMMI models already in place.

It is a fundamental principle of research design that only one variable should be modified at a given time, such that any observed differences can indeed be attributed to the change in that variable. Accordingly, CMS should postpone any nationwide Part B demonstration until it has had an opportunity to analyze the results of other ongoing models. Imposing the proposed Phase 1 and Phase 2 models on top of ongoing initiatives will compromise the validity of data obtained in both the existing CMMI models and the Phase 1 and/or Phase 2 models. There would be no way to determine which model had produced a given outcome.

D. The Issues Identified Here Raise Questions about the Ethics of the Proposal Itself

Congress enacted limits on the demonstration authority granted to the Agency because it fully appreciated the underlying ethical issues that would arise if Medicare beneficiaries were subjected to experimental demonstration projects, without the appropriate safeguards in place. Statutory differentiation of Phase I and Phase II models based on size and scope and the attendant safeguards Congress specifically put in place show that Congress understood well that demonstration projects could, if not undertaken properly, be unethical. Accordingly, the statute’s requirements are designed to limit the number of beneficiaries exposed to an experimental demonstration project and to ensure that health care quality will not deteriorate under a tested model.

It is fundamental to the conduct of any experiment that the entity undertaking that experiment act in an ethical manner with respect to the participants in that research. It is unethical for an entity to test a hypothesis on a population that is more extensive than necessary. The proposal’s failure to observe the Congressional limits on examining only new, innovative models that are to be tested only on defined populations, accordingly, is not merely a legal problem, but also an ethical one.

While CMS states that a demonstration must be large enough that differences in outcome are not caused only by random variation, there are equally important reasons to limit the size of an experiment to that necessary to test the hypothesis. No other demonstration is this vast in scope, and it is deeply concerning for the Agency to take the position that the scope of this proposed Phase 1 model is necessary to test its hypotheses. The Proposed Rule offers no statistical analysis to support this position, and the smaller scope of current demonstration projects appears to be inconsistent with the vast scope proposed here. In raising this bioethical concern, we highlight a point that other stakeholders have already articulated and that, significantly, the Administration has itself acknowledged.

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28 See discussion of existing CMMI models at supra note 24.
As the Presidential Commission for the Study of Bioethical Issues opined in its 2015 Report, a sample size that is too large “would expose more participants than necessary to research risks,”29 Explained another way, “the value per participant declines as the sample size increases.”30 Thus, once an experiment has a sufficient number of participants, larger sample sizes will subject many more individuals to burdens while offering disproportionately small increases in the study’s value.31

As we detail below, there are concerns about the proposed Phase 1 model’s impact on care access and treatment continuity. Exposing more individuals than is necessary to these risks is not consistent with the principles of research ethics. We urge the Agency to reconsider its position.

E. CMS Failed to Propose Metrics to Ensure that Care Quality Is Not Compromised.

The CMMI models enacted thus far include metrics to assess outcomes.32 Notwithstanding that, the Agency did not propose any care quality measures or outcome metrics under the Proposed Rule. This is disturbing in its own right, but it is also inconsistent with the statute, which specifies that CMMI models must maintain or improve care quality.33

The fact that this approach, absent any quality metrics or measures, is inconsistent with both the letter and the spirit of the statute is bolstered by the fact that CMS has taken steps to propose specific quality measures in other CMMI innovation models.34 Stakeholders, Astellas among them, are concerned that the lack of quality metrics means that there is no mechanism for CMS to ensure that patients are not harmed through its experiment.

Analyzing claims data as a proxy for care quality would be entirely inadequate because, in extrapolating from claims data to conclusions about care quality, significant assumptions must be made, which greatly reduce the validity of any conclusions that can be drawn from such an

30 Peter Bacchetti et al., Ethics and Sample Size, 161 AM. J. EPIDEMIOLOGY 105, 105 (2005).
31 Id.
33 42 U.S.C. § 1315a(a).
34 For instance, the CCJR model will assess quality provided by participating hospitals by comparing their performance on certain metrics outlined in the Hospital Inpatient Quality Reporting program with the performance of hospitals generally. Specifically, the quality metrics include the risk-standardized complication rate following elective primary total hip or knee arthroplasty, the 30-day all-cause readmission rate following elective primary total hip or knee arthroplasty, and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure. 80 Fed. Reg. 73274, 73465 (Nov. 24, 2015).
analysis. In the absence of direct quality data, deterioration in care quality is likely, but may not be identified before beneficiaries are harmed. CMS’ first duty is to protect its beneficiaries.

F. CMS Did Not Utilize a Process to Solicit Input from Stakeholders, as Statutorily Required, Before Selecting Its Proposed Approach.

“[I]n carrying out the duties under this section,” the statute quite clearly requires CMMI to: “consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMMI shall use open door forums or other mechanisms to seek input from interested parties.”

Astellas is concerned by the lack of stakeholder involvement in the process of designing the Proposed Rule. Congress specifically provided for robust involvement by “interested parties.” The Agency, however, failed to meet this mandatory statutory requirement to engage interested parties through open door forums or similar mechanisms in its selection of the proposal.

While the Department of Health and Human Services sought to engage stakeholders on the topic of pharmaceutical pricing in a forum hosted late last year, this forum did not raise the issue of whether ASP add-on rates should be reduced as a strategy to address spending or to test its potential impact on prescription decisions. It did not discuss what cut might be tested, what the likely impacts would be on patients, the geographies that might be selected for the experimental and control arms, what exclusions should apply, the size of the population that would be needed to test any hypothesis, the duration of any test, the timing for implementation, what quality metrics or measures should be employed, or any other relevant topic, all of which bear on the critically important issues of maintaining quality of care and the risks posed to participants.

The requirement to seek input from interested parties is rendered meaningless if the Agency does not seek feedback on the specific proposals it is considering.

G. Phase I Models Cannot Be Enacted if They Are Not Supported by Evidence.

The statute provides that models tested by CMMI must meet specific selection criteria under paragraph (b)(2) of the statute. Under that paragraph, models that the Secretary may select are limited to those for which there is evidence that the model addresses a defined population with care deficits and associated poor clinical outcomes or avoidable expenditures. However, the Phase 1 model is not supported by evidence and, thus, cannot be implemented.

To support the reduction in the ASP add-on percentage, CMS relies on a 2015 Medicare Payment Advisory Commission (“MedPAC”) report, which suggested that the “6 percent add-on to ASP may create incentive [sic] to use higher priced drugs. Because 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug has the potential to generate more profit.”

35 42 U.S.C. § 1315a(a).
36 42 U.S.C. § 1315a(b)(1).
37 MedPAC, Report to the Congress: Medicare and the Health Care Delivery System (June 2015) at 68.
Any fair examination of the MedPAC report reveals that it cannot reasonably be used to support the suggestion that providers’ drug selections are, in fact, influenced by a drug’s ASP markup. In the report, MedPAC cites only two studies, neither of which illustrate a strong association between a drug’s ASP and treatment selection.\textsuperscript{38} For instance, one study examines a number of treatments for lung cancer and, according to MedPAC “suggests that drug choice may to some degree be influenced by the higher add-on.”\textsuperscript{39} Further, MedPAC itself acknowledged that “it is difficult to know the extent to which the percentage add-on to ASP is influencing drug prescribing patterns because few studies have looked at this issue.”\textsuperscript{40} Given MedPAC’s clear statement that there is no data supporting a link between ASP add-on rate and prescribing patterns, stakeholders do not perceive CMS’s adoption of the proposed Phase I model as being based on evidence that would justify putting the health of millions of Americans at risk.

Again, this raises a bioethics issue, which is why Congress imposed the evidence requirement that it did. An appropriate research question requires a meaningful reason to believe that the research, which will inevitably expose patients to risks, justifies the imposition of those risks. In addressing that question, an entity undertaking research is obligated to consider all available data and to ensure that the hypothesis is reasonably supported by sufficient existing data.

Here, the Proposed Rule fails to indicate that these basic requirements have been met. We urge the Agency to reconsider these issues in light of these fundamental legal and ethical concerns.

H. CMS Has Not Satisfied the Phase I Evaluation or Other Procedural Requirements.

As noted above, the statute only allows for an expanded demonstration, like the one that the Agency seeks to implement for Phase 1, where the results of a test on a defined population provide an adequate basis for that expansion. Contrary to the statute, the Agency’s proposed Phase I model skips immediately to what can only fairly be seen as a Phase II model. The Agency does so, however, without fulfilling the important procedural safeguards that must be satisfied in connection with the completion of an appropriate Phase I effort or the initiation of a Phase II project.

Importantly, before ever proceeding to an “expansion” under Phase II, including a “nationwide” program, the Secretary is required to conduct an evaluation to analyze the quality of care and the spending changes of “each model tested.”\textsuperscript{41} The statute explicitly limits permissible demonstrations to those that will enhance, or at least maintain, the quality of care provided to beneficiaries, based on the completion of a Phase I effort.\textsuperscript{42} This safeguard is not a trivial matter; it is in the statute to ensure that any desired cost savings do not come at the expense of inferior care for Medicare beneficiaries. The evaluation is a necessary step to ensure that care quality is not compromised.

Further, in Phase 2, the Agency proposes to develop concepts, such as reference pricing, indication specific pricing, and value-based arrangements that it has failed to include in Phase 1.

\textsuperscript{38} Id.
\textsuperscript{39} Id.
\textsuperscript{40} Id. at 62.
\textsuperscript{41} 42 U.S.C. § 1315a(b)(4).
\textsuperscript{42} 42 U.S.C. § 1315a(a)(1).
Phase II expansions can only be undertaken where Phase I data on “each model tested”\(^{43}\) has been evaluated at the end of Phase I. None of these different concepts can be included in Phase 2, because they are not being tested in Phase 1, and will not, therefore, be evaluated at the completion of Phase 1.

The transition from Phase 1 to Phase 2 would also require a new, separate rulemaking obligation, which is absent here. The Proposed Rule before us now does not suffice, as the required rulemaking must “take[e] into account” the Phase I evaluation, and, as such, the statutorily required Phase II rulemaking cannot be commenced until Phase I has been implemented and analyzed. In addition, the statute requires that the Chief Actuary of CMS certify that the Phase II expansion will reduce (or at least not increase) Medicare spending and that the Secretary make multiple findings as to Phase I. No such certification has been obtained. The Agency does not have the legal authority to disregard the patient protections required by Congress.

I. Perhaps, Most Fundamentally, the Proposal Is So Vague and Indeterminate, that It Fails to Provide Meaningful Notice and Opportunity for Comment, as Required by the APA.

The Proposed Rule fails to meet the notice and opportunity for comment requirements imposed by the Administrative Procedure Act (“APA”).

The courts have been clear that a notice of proposed rulemaking must present the agency’s views “in a concrete and focused form so as to make criticism or formulation of alternatives possible.”\(^{44}\) This includes a requirement that the agency “must describe the range of alternatives being considered with reasonable specificity.”\(^{45}\) “Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking.”\(^{46}\) “Failure to make known agency views at the time of publication of notice circumvents the purpose of the APA notice requirements. Proposed rule changes cannot be ‘tested’ when the public is unaware of both the proposed revision and the theory under which the agency makes its proposal.”\(^{47}\)

The Proposed Rule does not meet these requirements. The Agency fails, for instance, to explain which jurisdictions will be in the “experimental arm” and which in the “control arm” during Phase 1. This makes it impossible for any stakeholder to determine if this one feature of the proposed Phase 1 model may have a disproportionate impact on sub-populations, persons affected by particular diseases or conditions, beneficiaries with lesser economic means, beneficiaries from minority groups, and other critically important factors.

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\(^{43}\) 42 U.S.C. § 1315a(b)(4).


\(^{45}\) Id. at 549.

\(^{46}\) Id.

Phase 2 discussed using undefined terms, such as “reference pricing,” “indications-based pricing,” and “value-based” payments, without providing any meaningful information about what the Agency is actually considering and what beneficiaries, geographies, and drugs will be affected. With regard to reference pricing, for instance, the Proposed Rule does not address any of the most basic questions, such as what prices would be referenced, and from what geographies, programs, payors, or time periods.


A. Lowering ASP Payments Threatens Patient Access to Treatments and Could Lead to Providers Not Providing the Most Clinically Appropriate Service to Patients.

Although it has no evidence to support it, CMS’ Proposed Rule, at its core, is based on the assertion that there “may” be some connection between higher ASP reimbursement rates and the use of higher cost products. The few sources CMS cites for this assumption do not purport to claim that clinically inappropriate drugs are selected based on the ASP reimbursement afforded to date. CMS contends that providers select treatments not based on the most clinically appropriate therapy, but rather based on the drug’s reimbursement.

As a threshold matter, Astellas does not believe that this assumption accurately portrays the practice patterns of America’s health care professionals. We believe that physicians and other practitioners are committed to putting patients’ health first, and will choose the treatment that is, in their clinical judgment, the most appropriate for the patient. In some cases, this will be a drug that costs more than the average drug, while in other cases the less expensive treatment will be more effective. Providers may test a number of products before choosing the treatment to pursue, ultimately selecting a treatment based on the patient’s response to the therapy. Indeed, the available data shows great variability in which (branded or generic) drug options physicians and other practitioners choose after consulting with their patients.

But even the most dedicated health care professional cannot be expected to put his or her practice and family at risk by supplying treatments that are not adequately reimbursed by the Medicare program. When payment for Part B drugs drops below the level needed to cover the provider’s costs, the treatment options that a provider can make available may inevitably be limited such that the patient may not have access to the treatment option that is in the patient’s best clinical interest.48

Given the proposed reimbursement reduction, there is a risk that providers will operate at a loss when administering Part B drugs. Under the proposed Phase 1 model, products will be reimbursed at their ASP plus 2.5%, reduced by the sequestration amount; this effectively means that CMS will pay just 0.86% more than a product’s ASP.49 Although an additional amount of $16.80 will be paid for each drug provided, a vast number of drug reimbursements and the

48 The Agency must also anticipate the risk that a number of Medicare beneficiaries will not pay the co-insurance amounts associated with their therapy.
49 Under the Phase 1 intervention arm, CMS would set the pre-sequestration payment rate for most Part B drugs at 102.5% of ASP + $16.80 (with the $16.80 being paid “per drug per day administered”). 81 Fed. Reg. at 13240. After the 2% sequestration cuts, this payment rate would be 100.86% of ASP.
providers who depend on them will be “under water” whenever they select the most clinically appropriate drug option.

Further, as the Agency is aware, based on the customary prompt pay reports that manufacturers make each reporting period under the Medicaid program, wholesaler prompt pay discounts alone, even putting aside the many other discounts present in the marketplace, mean that the average provider acquiring any relevant Part B product may often be “under water” as a consequence of this proposed Phase 1 model. When the impact of discounts and rebates to managed care entities, Pharmacy Benefit Managers (“PBMs”), and others are considered, the fundamental inadequacy of the proposed Phase 1 model becomes evident, even for lower cost drugs, given the very limited additional support provided by the $16.80 flat fee.

There are two basic reasons why, contrary to the Agency’s contention, use of lower than average cost therapies and higher than average cost therapies will not even out. First, many specialties, as CMS’ own analysis reveals, are associated with higher than average cost drug therapies. For a disease that requires more costly drugs, for instance, there is no opportunity for the providers focusing on that disease to balance higher and lower cost drugs. For many practices, the only treatment options involve drug products that have higher than average acquisition costs. This will be particularly true in orphan drug populations and in areas where the newest, most innovative therapies have been developed and introduced.

Importantly, these cost barriers are likely to have the effect of shifting care from the physician office setting to the hospital setting. This should be a source of concern to the Agency, as treatments in the hospital setting are associated with higher costs. Additionally, this shift puts sick patients at further risk by exposing them to environments that have a higher infection rate. The rate of hospital-acquired infections remains high; the consequences of a hospital-acquired infection can be grave, particularly in patients with compromised immune systems. These quality of care risks would be inherent in this proposal.

Secondly, as we just noted above, the proposed Phase 1 model reimbursement rate is so inadequate that even access to lower than average cost drug therapies may be impacted by the Phase 1 model. This underscores why, in our view, and in the view of many other stakeholders, the models set forth in the Proposed Rule constitute a serious risk to access to care and to the health of Medicare beneficiaries.

Indeed, the Agency itself has acknowledged that the Phase 1 model in the Proposed Rule risks inappropriately altering care decisions. As the Proposed Rule states, “we are concerned that an

50 81 Fed. Reg. at 13233.
52 Centers for Disease Control and Prevention, National and State Healthcare Associated Infections: Progress Report 2016, at 6 (reporting that, in 2014, one in 25 hospital patients has at least one hospital-acquired infection).
add-on that is roughly equal to or slightly more than the cost of a drug may still leave some incentive for overusing some inexpensive drugs.”53 We fear that patients will be harmed by the overuse of “some inexpensive drugs,” where, often, the use of a single drug, even at a higher cost, would be the more appropriate clinical option for the beneficiary. The risks to quality of care and to increased costs for the system as a whole are all too real.

The concerns that the Agency itself has raised, then, not only indicate that the Phase 1 model is not an appropriate policy choice, but that the Phase 1 model cannot meet the statutory requirement that the demonstration “preserv[e] or enhance[e] the quality of care furnished to individuals” under the Medicare program.54 This, again, demonstrates that the Phase 1 proposal is in excess of the Agency’s authority.


Astellas supports the Agency’s efforts to encourage a healthcare delivery system that rewards value and believes that, when appropriately implemented, value-based arrangements hold promise for improving patient outcomes and promoting innovation. However, Astellas is concerned that the Agency has proposed a demonstration that does not promote value, but rather institutes cost-cutting measures, across the board, without regard to the value of the therapies affected. As currently designed, the Proposed Rule threatens access to medicines that are widely recognized as providing value, as the most appropriate option for appropriate patients. Instead of rewarding value, the Proposed Rule indiscriminately targets all therapies, risking a deterioration in health outcomes and quality of care.

Further, the Proposed Rule threatens pharmaceutical innovation, precisely because it fails to offer anything other than reimbursement cuts, regardless of how valuable a treatment is. Pharmaceutical innovation is an extremely costly endeavor, and the reimbursement available to drugs on the market is a serious consideration for manufacturers as they determine how to allocate finite resources. Although our company is committed to doing everything that we can to identify and address unmet medical needs, cost cuts as dramatic as what CMS proposes here will force some manufacturers to abandon various research and development efforts, no matter how promising they may be.

The threat to innovation is not limited to Phase 1. Phase 2’s proposal to introduce reference pricing, for instance, threatens to significantly stymie efforts to produce therapies that are better than therapies currently on the market. The prospect of being assigned a reference price that disregards differences between treatments would negatively affect development efforts. Unfortunately, reference pricing has meant that manufacturers have been unable to introduce a number of innovative therapies, including orphan drugs, in even some very prominent and economically strong markets in the European Union.55

54 42 U.S.C. § 1315a(a).
Astellas is firmly committed to innovation and to advancing its vision as a leader in developing medical solutions that address unmet needs. To that end, Astellas is focusing research investment efforts in areas such as muscle disease, ophthalmology, and regenerative medicine. These are areas in which, without innovation, no adequate therapy, or no therapy at all, is currently available. Astellas is willing to partner with CMS and engage in a dialogue regarding how value-based strategies can be implemented into the Medicare Part B system. Such an arrangement must put the patient first and encourage innovation by rewarding drugs that produce value and superior outcomes. Value-based strategies hold promise in promoting better therapies, a more sustainable healthcare system, and strong incentives to invest in innovation. The current Proposed Rule does not, however, meet these objectives, and should not be implemented.

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We thank you for the opportunity to comment. Astellas appreciates your consideration of these important issues. We would be happy to discuss any of these issues with CMS or provide any further information or analyses that may be useful to you; please do not hesitate to contact Emily Baron at 202-741-1966 or emily.baron@astellas.com with any questions, comments, or requests for additional information.

Sincerely,

Jeff Winton
Senior Vice President, Corporate Affairs

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reimbursement); Sandy Craine, Pfizer Withdraws Bosulif in Germany (Oct. 12, 2013), available at http://www.cmlsupport.org.uk/thread/10338/pfizer-withdraws-bosulif-germany (discussing that Pfizer would not market orphan cancer drug Bosulif® (bosutinib) in Germany due to the country’s pricing regime); Tracy Staton, Eisai Pulls Fycompa in Germany to Protest Pricing (Jun. 25, 2013), available at http://www.fiercepharma.com/sales-and-marketing/eisai-pulls-fycompa-germany-to-protest-pricing (explaining that the German pricing body’s determination that Fycompa® would be tied to reference price was the basis for Eisai’s withdrawal of the drug).