innovatix

innovatix.com

T (888) 258-3273 F (646) 638-2641

555 West 57th St., 12th Floor | New York, NY 10019

Innovatix is affiliated with PREMIER

May 6, 2016

The Honorable Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1670-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; Part B Drug Payment Model, CMS-1670-P

Dear Mr. Slavitt:

Innovatix is one of the nation's largest non-acute care group purchasing organizations, with a national membership of over 30,000 non-acute care providers, including approximately 650 long-term care pharmacies and 2,600 infusion providers. We understand that unsustainable growth in healthcare expenditures necessitates transformational reforms to ensure a future healthcare delivery system that can meet patient demand. However, following extensive discussions with our members, partners, and colleagues, Innovatix is compelled to raise serious concerns with the Centers for Medicare & Medicaid Services proposed rule, "Medicare Program; Part B Drug Payment Model (CMS-1670-P)," which aims to control drug costs. We believe that *both* Phase I and Phase II of the proposed demonstration project may have unintended, harmful consequences for beneficiaries and for the providers treating them. Further, we believe both Phases are overly far- reaching in terms of their timeframe and scope, and warrant additional consideration and input from the stakeholders impacted by the proposed rule.

Patient Safety and Access and the Need for a Comprehensive Clinical Model

Any Medicare Part B reimbursement changes that the CMS makes must account for the complexities of patient care across the healthcare continuum. The current Medicare Part B drug reimbursement methodology of an average sales price (ASP) +6.0% is far from perfect due to many factors, such as the applied sequestration cut and the time lag from when manufacturers report pricing to when this data is used to update the ASP benchmark. While the current model has the potential to create reimbursement challenges for providers, it does offer some level of stability, which providers have been able to successfully navigate to ensure consistent patient access. We are concerned that the proposed payment model will create significant instability in reimbursement, leave providers with little flexibility to treat their patients, and may possibly force some beneficiaries into more costly sites of care. The proposed rule focuses on creating incentives so that beneficiaries ultimately receive drugs at a lower cost. However, this narrow view of reform is problematic because a less expensive drug may not be the best treatment option for a particular patient, i.e., it may not be as effective as more costly alternatives or may cause serious side effects. Rather than focusing predominantly on containing drug costs, we urge the CMS to

move to a comprehensive clinical management model that recognizes and creates specific reimbursement incentives to pay providers for professional services, supplies, and the education necessary to treat the whole patient who requires Part B drugs.

The current ad hoc and fragmented home infusion payment structure is a prime example of why comprehensive and thoughtful reform is necessary. Infusion therapy consists of three components of care: the infusion drug, the supplies and equipment necessary to deliver that drug, and the professional services required to safely and effectively administer the therapy. Rather than seeking treatment for serious conditions in hospitals, nursing homes, and hospital outpatient departments, home infusion allows patients to resume a normal lifestyle and work activities, and, in doing so, provides them with the opportunity for a better quality of life. The service component of home infusion drugs is covered under neither Medicare Part B nor D; since 2003, the average wholesale price for Part B durable medical equipment drugs has often been sufficient to cover the costs associated with home infusion services. Innovatix, along with its partners, has long advocated for a comprehensive home infusion benefit, such as The Medicare Home Infusion Site of Care Act of 2015 (H.R.605/S.275), which would reform the payment of infusion drugs and add a service component that is necessary to safely and effectively administer infusion drugs. In doing so, the Medicare program would realize program savings as beneficiaries received care in less costly settings.

We thank the CMS for already working with Congress on meaningful home infusion reform and we urge the agency to continue to prioritize this issue. The agency must ensure the proposed Medicare Part B Drug Payment Model will not interfere with the progress already being made to provide Medicare beneficiaries with a comprehensive home infusion benefit.

> *<u>Recommendation:</u> Rather than focusing only on drug costs, the CMS must advance a comprehensive clinical management model that recognizes and creates specific reimbursement incentives to pay providers for professional services, supplies, and the education necessary to treat the whole patient who requires Part B drugs. Additionally, the CMS should continue working alongside Congress to advance The Medicare Home Infusion Site of Care Act.*
>
> *Similarly, the CMS should examine how reimbursement changes may restrict patient access and reduce patient safety before implementing such reforms. Further, we urge the CMS to have a clear process evaluation with real-time monitoring in place to address any unintended consequences that may arise from the demonstration.*

<u>Implementation Concerns: Timeline and Scope of the Proposed Rule</u>

Innovatix is concerned that the start time for the demonstration—which would launch Phase I as early as Fall 2016 and Phase II in January 2017—is too soon and too compressed. The proposed

rule creates a number of structural changes that are likely to fundamentally disrupt and change the market, making it difficult for providers to plan or anticipate how their practice may be impacted. Without knowing where they fit into the proposed rule, many providers have been challenged to supply the CMS with substantive comments on the specifics that the CMS requests in the proposed rule. For instance, pharmacies need to know their upfront reimbursement to best administer medications for their patients; this proposed rule does not build in an appropriate timeline or provide enough guidance for providers to prepare for Phase I or Phase II. Furthermore, the CMS proposes the model would run for five years, which is too long for those providers that would be adversely affected by the model. This is especially true given the structure of Phase I, where certain providers will be forced through random selection to immediately accept a different methodology than the current ASP +6.0%.

In addition to our timeline concerns, the scope of the proposed rule is too expansive. The CMS proposes to apply mandatory changes to Medicare payments for nearly all Part B medications to all states with the exception of Maryland due to its all-payer model. A demonstration should be tested using a more focused sample so that unintended consequences can be properly assessed and resolved before making requirements that can impact the majority of the Medicare population. Our main concerns with the accelerated timeline for implementation, the lengthy duration of the model, and the inappropriate scope of the rule is that the CMS has not provided any details in the proposal on how it plans to respond should the model yield unintended negative consequences, falter, or result in reduced access to services for Medicare Part B beneficiaries. We believe the CMS must provide details on plans for how it will respond should the model fail and create provider and patient access problems.

> *<u>Recommendation:</u> The CMS should not move forward with the proposed implementation timeline and scope until adequate stakeholder input is provided and it has detailed plans to address potential provider, patient access and safety issues created by the model. Furthermore, the CMS should scale back the duration of the demonstration to no more than 3 years and select a more focused sample of participants that has been vetted by the appropriate stakeholders.*

<u>Stakeholder Engagement</u>

Given that the proposed rule covers the entire country and would apply to any provider who offers prescription drugs that are covered under Medicare Part B, the CMS would benefit from more active stakeholder involvement from the groups potentially impacted by the proposed rule. Engaging stakeholders before finalizing the rule will help prevent the unintended consequences described above and help the CMS to better meet their cost, quality, and patient outcome goals. The CMS should actively seek stakeholder engagement beyond this limited 60-day comment period, especially through a rulemaking process for the Phase II payment models. We would oppose a sub-regulatory approach because it is problematic for the stated goals of the proposed

rule given the dearth of information for stakeholders to adequately weigh-in during this limited comment period. This process should result in the development of a final rule that is operationally and financially viable for providers. Stakeholder engagement should occur in advance of the implementation of Phase I and Phase II to allow adequate time for providers to determine how they can continue serving Medicare Part B beneficiaries.

> *Recommendation: The CMS should actively seek stakeholder engagement beyond the 60-day comment period to develop a model that is operationally and financially viable for providers. The CMS should use the rulemaking process (i.e., not a sub-regulatory approach) for Phase II in order to properly consider stakeholder concerns with the initiative. The rule should be finalized by the CMS well in advance of the implementation of Phase I.*

Innovatix looks forward to working with the CMS and other stakeholders to develop reforms that meet the CMS' goals and are appropriate for beneficiaries and providers. Innovatix has significant concerns about the current parameters of the Part B Drug Payment Model, especially the unintended consequences for patient safety and access, the sudden yet extended timeline and the need for broader stakeholder engagement. Thank you for considering these important issues and please contact Shara Siegel, Director of Government Affairs at ssiegel@innovatix.com or (212) 901-1264 with any questions.

Sincerely,

John P. Sganga, FACHE
Executive Vice President, GNYHA Ventures
President & CEO, Innovatix
President & CEO, Essensa