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SPECIALTY PHARMACY**

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May 9, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

cc: Susan Janeczko
Health Insurance Specialist
Center for Medicare

BY ELECTRONIC DELIVERY

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

Dear Acting Administrator Slavitt:

The National Association of Specialty Pharmacy (NASP) appreciates this opportunity to submit comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule entitled, "Medicare Program; Part B Drug Payment Model" (Proposed Rule).¹ NASP is a non-profit trade organization representing a wide range of stakeholders in the specialty pharmacy industry. NASP has 71 corporate members and 1,200 individual pharmacists making it the leading unified voice of specialty pharmacy. Our members include the nation's leading independent specialty pharmacies, pharmaceutical and biotechnology manufacturers, Group Purchasing Organizations (GPOs), patient groups, wholesalers/distributors and practicing pharmacists. Our members constantly refine the practice of specialty pharmacy with a single focus on the patients we serve to ensure better outcomes while reducing overall healthcare costs. NASP is also the leading education resource for specialty pharmacists and provides an online education center with over 30 continuing pharmacy education programs, hosts an annual meeting that offers 27 education sessions, and operates a certification program for specialty pharmacists.

NASP represents an industry that focuses on providing quality patient care first with an added emphasis on outcomes and patient choice. NASP believes that it shares these common goals with CMS and looks forward to partnering with the agency to ensure that all Medicare beneficiaries receive high quality cost effective care from their specialty pharmacy. Through this lens, NASP submits our comments below related to the Proposed Rule.

¹81 Fed. Reg. 13230 (Mar. 11, 2016).

I. Restatement of Definition of Specialty Therapy and Specialty Pharmacy

In order to appropriately frame NASP's discussion on the Proposed Rule, below please find the definitions of both Specialty Pharmacy and Specialty Medications. NASP submitted these definitions as part of our comments to the 2017 Call Letter and repeats them here such that our discussions on the subsequent policy issues, particularly related to access, within the Proposed Rule can be read in the context of these foundational definitions. The definitions share the significant theme of high touch patient services. For example, a specialty drug is defined by the many services provided in support of appropriate access, and a specialty pharmacy is the state licensed and third party accredited entity providing those high touch patient services.

A. Definition of Specialty Therapy

Specialty drugs, or medications, are more clinically complex than most prescription medications and are used to treat patients with serious and often life threatening conditions including cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, hemophilia and other bleeding disorders. Specialty therapies can be injectable, infusible, oral or inhaled and tend to be more complex to maintain, administer and monitor than traditional drugs. Therefore, they require closer supervision and monitoring of a patient's overall therapy. Because of the complex clinical profile, intensive and extensive patient engagement by the specialty pharmacist is required. For example, many specialty therapies require significant patient education on both the disease and the prescribed therapy. Many specialty pharmacists have specialized areas of clinical expertise, which the prescribing physician relies upon to help explain the nature of the disease. Furthermore, this pharmacist then explains to the patient the prescribed regimen for the prescribed drug. It is through these services that the specialty pharmacist acts as an extension of the physician's office to educate the patient on his/her disease and empowers the patient to use the therapy appropriately. This education is a very important part of improving beneficiary outcomes and reducing unnecessary drug and healthcare spend.

Further, the specialty therapy may be classified as such due to the way it is administered, the side effect profile, the disease or condition it is used to treat, special access conditions required by the manufacturer, payer authorization or benefit requirements, patient financial hardship, special handling, or any combination of these. Based on these characteristics, the payer, provider, specialty pharmacy and/or the manufacturer can or will identify the therapy as requiring the aforementioned specialized services. As a result, specialty prescription medications cannot be routinely dispensed at a typical retail community pharmacy because the typical retail pharmacy does not have the required infrastructure to deliver the personalized, high touch level of patient care or other support services that specialty medications require. Lastly, specialty drugs are often confused as being only a "limited distribution drugs (LDD)". This is not the case as there are specialty drugs that are not part of a limited distribution network.

Cost should not be the only reason a therapy is classified as specialty. In fact, there are many low cost therapies that are classified as specialty because of the extensive clinical knowledge, expertise and unique labor intensive services required to assure proper utilization and maximize the clinical outcome. For example, select generic oral chemotherapy medications and certain generic immunosuppressant medications require special handling processes and a comprehensive, coordinated care approach to ensure successful therapeutic outcomes similar to those of higher cost therapies. Even though these therapies are low cost, they are still considered specialty therapies by plan sponsors. A therapy's classification should be based on the services provided in support of the therapy and not just its cost.

B. Definition of Specialty Pharmacy

As a result of the growth of specialty therapies, the practice of specialty pharmacy has also evolved. The expert services that specialty pharmacies provide drive adherence and persistency, proper management of medication dosing and side effects, and ensure appropriate medication use. The specialty pharmacy's patient-centric model is designed to provide a comprehensive and coordinated model of care for patients with chronic illnesses and complex medical conditions, achieve superior clinical and economic outcomes, and expedite patient access to care.

A specialty pharmacy is a state-licensed pharmacy that solely or largely provides medications for people with serious health conditions requiring complex therapies. These include conditions such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia and other bleeding disorders. In addition to being state-licensed and regulated, NASP believes that specialty pharmacies should also be accredited by independent third parties. Accreditation represents a commitment to quality, safety and accountability.

Accreditation organizations help pharmacies develop their specialty pharmacy capacity and verify their capabilities to manufacturers and third-party payers. The prominent accrediting bodies are URAC®², the Accreditation Commission for Health Care (ACHC)³, the Center for Pharmacy Practice Accreditation (CPPA)⁴ or the Joint Commission.⁵ Each of these organizations create standards that are designed to create a consensus around the practice of specialty pharmacy and guide the accreditation process. In general, the standards can address four primary areas of specialty pharmacy practice, which encompass the overall provision of pharmacy care for patients receiving these medications. These areas of focus include the organizational infrastructure to support the provision of specialty pharmacy care, patient access to medications via

² <https://www.urac.org/accreditation-and-measurement/accreditation-programs/all-programs/specialty-pharmacy/>

³ <http://www.achc.org/programs/pharmacy/pharmacy-accreditation-process>

⁴ <https://pharmacypracticeaccredit.org/our-programs/specialty-pharmacy-practice-accreditation-program>

⁵ http://www.jointcommission.org/accreditation/accreditation_main.aspx

manufacturer requirements and benefits investigation, clinical management of the patient, and quality. The accreditation process further ensures that Medicare beneficiaries receive consistent quality of care.

Specialty pharmacies serve a critical role in the healthcare system because they connect patients who are severely ill with the medications that are prescribed for their conditions, provide the patient care services that are required for these medications, and support patients who are facing reimbursement challenges for these highly needed but also frequently costly medications. Specialty pharmacies do not establish the price of the specialty drug, but are a significant partner in driving the value of the drug towards a successful therapeutic outcome.

II. NASP Is Concerned with the Broad Scope Of the Part B Drug Payment Model

CMS proposes a new Medicare payment model (Payment Model) under section 1115A of the Social Security Act (SSA) to “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.”⁶ The proposed methodology would be implemented over two phases. The first phase would change the 6 percent add-on to the Average Sales Price (ASP) methodology to 2.5 percent plus a flat fee (in a budget neutral manner). The second phase of the Payment Model would implement “value-based purchasing tools similar to those employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization.”⁷ NASP understands, appreciates, and shares CMS’ goals “of smarter, that is, more efficient spending on quality care for Medicare beneficiaries”⁸ but has serious concerns related to the agency’s process in developing the Proposed Rule and some of the Proposed Rule’s concepts to achieve these goals.

NASP’s members interact with and are often in the middle of many of the Medicare Part B stakeholders that the Proposed Rule aims to affect. As stated below, there are many important classes of drugs that the agency proposes to include in the Payment Model that are predominately distributed by specialty pharmacies such that specialty pharmacies have a unique insight on how the Proposed Rule will impact Medicare beneficiaries, providers, suppliers, payers, and manufacturers. No other stakeholder in the healthcare system interacts with so many other stakeholders, especially given the routine clinical involvement that the specialty pharmacy has with each Medicare beneficiary.

NASP is concerned that the Proposed Rule, which proposes significant changes to the healthcare system, was developed and issued without any initial stakeholder input as to process for development, goals of the demonstration and methodology for

⁶ Id. at 13230.

⁷ Id.

⁸ Id.

implementation. NASP is tracking the agency's effort to implement the Alternative Payment Models (APMs) and the Merit-Based Incentive Payment System (MIPS) required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which included a RFI process and an opportunity to comment through the annual Physician Fee Schedule update. NASP believes that similar to that major transition in physician payments for service, the agency should have, at a minimum, issued a RFI for this proposed major transition for payment of drugs and biologicals administered incident to a physician's office visit. The agency's lack of including other stakeholders in developing the Proposed Rule is troublesome, which likely led to proposals that are too broad, lack many important details and are misguided in certain respects. In fact, NASP believes that the Proposed Rule will likely not accomplish CMS' stated goals of eliminating incentives related to prescribing. Rather, the proposals will only transition the incentives to other classes of drugs or, worse, incentivize the treatment of more Medicare beneficiaries in the outpatient hospital setting, which is likely not in the beneficiaries' or Medicare program's best interest.

CMS proposes to require that all providers and suppliers participate in the Payment Model if they are furnishing Part B drugs that are included in the model and are located in a geographic area that is chosen for participation in the Payment Model.⁹ CMS is therefore implementing a new Payment Model affecting many stakeholders within the healthcare system, including millions of vulnerable Medicare beneficiaries that is mandatory and nationwide without any experience as to how any aspect of either Phase 1 or Phase 2 of the Payment Model will affect access to care. NASP is concerned with this broad utilization of the agency's demonstration authority, especially since CMS has no previous experience implementing any kind of program of this scope or nature in such a short time frame. Further, the agency had not described how the Payment Model will improve patient outcomes or quality to be consistent with and not in opposition to other agency initiatives related to improved outcomes. NASP believes that the agency must proceed with caution and with what is in the best interest of the Medicare beneficiary and not any other particular stakeholder, especially given the potential for the adverse impact of beneficiary access and care without the agency's corresponding justifications related to preventing these potential negative outcomes.

CMS states that its proposals are similar to those employed by commercial health plans, pharmacy benefit managers and other stakeholders; yet, those entities serve a different population and those programs were never initially implemented on such a large scale. NASP is concerned that the agency's comparison to those programs is misguided and inaccurate. Our members worked closely with the sponsors of the programs that CMS refers to in order to help implement those types of alternative payment models. At each turn, there was a robust and significant education program focused on the provider and patient. Additionally, the alternative models that NASP's members participated in that were launched in the private sector, started small, were well supervised, and contained significant efforts around coordination of care to ensure and preserve appropriate access to needed therapies and the data integrity of the model. CMS, however, suggests that the Payment Model will be implemented no

⁹ Id. at 13232.

earlier than 60 days after the display of the final rule. NASP strongly suggests that any implementation deadline take into consideration the magnitude of the task to implement a nationwide mandatory program and therefore hopes that there is much longer than a 60 day implementation period should one exist. Additionally, if the agency moves forward, it should detail its education plan on how best to inform beneficiaries and prescribers as to this significant change. Based upon our experiences, NASP's members are concerned that the Proposed Rule does not contain enough detail related to program implementation to preserve appropriate beneficiary access to needed therapies, and as described further below, tests financial incentives that do not exist.

III. Should the Part B Drug Payment Model Move Forward, NASP Urges CMS To Exclude Drugs Outside of the “Incident To” Setting

A. There is NO Financial Incentive Attached to the Non-Incident To Drugs

NASP believes that drugs covered under Medicare Part B that are provided outside the “incident to” benefit category should be excluded from Phase I of the Payment Model as these drugs do not satisfy CMS’ stated purpose and scope of the Payment Model. Specifically, CMS states that

“our goal is to minimize providers’ and suppliers’ financial incentives to prescribe more expensive drugs.”¹⁰ Further, CMS states that “we intend to achieve savings through behavioral responses to the revised pricing, as we hope that the revised pricing will remove any excess financial incentive to prescribe high cost drugs over lower cost ones when comparable low cost drugs are available. In other words, we believe that removing the financial incentive that may be associated with higher add-on payments will lead to some reduction in expenditures during phase I of the proposed model.”¹¹

NASP therefore understands that one of the main purposes of the model is to understand prescriber behavior once the financial incentive is disconnected from the prescription. If this is the case, NASP questions why CMS includes drugs where this financial incentive does not exist because the prescription does not generate revenue to the prescriber.

CMS answers this partly by stating that “it is important for the model to include drugs that are used outside of the incident to setting”¹² and therefore includes non-infused drugs furnished by DME suppliers (including the limited number of Part B Drugs dispensed by pharmacies), such as immunosuppressive, oral chemotherapy, oral antiemetics, inhalation drugs used with DME, and clotting factors. The agency states no other reason besides “it is important to include these types drugs” with no financial incentive to the prescriber that helps NASP and Medicare beneficiaries understand how

¹⁰ 81 Fed. Reg. 13239.

¹¹ 81 Fed. Reg. at 13233.

¹² 81 Fed. Reg. at 13235.

this offsets the access risk and potential disruption in care presented by the Payment Model.

These classes of drugs treat vulnerable Medicare beneficiaries whose adherence to their drug regimen is important to their survival and often to saving healthcare dollars and resources. As such, if the benefits of the Payment Model do not exist for these classes of drugs, why include them thereby taking the risk that these vulnerable populations may experience access to care issues. Beneficiaries requiring an immunosuppressant, clotting factor or chemotherapy are at risk for much greater healthcare utilization if they deviate from their regimen and as such any change to their routine must have greater upside than is stated by CMS by including these classes of drugs in the Payment Model. For example, NASP believes that a potential unintended consequence of including these types of drugs, especially the immunosuppressant drug class, is that specialty pharmacies may not be able to consistently supply the same generic product. Rather, the specialty pharmacy may be forced to choose a different generic drug at the time of dispense, due to fluctuations in the generic drug marketplace that often occurs as a result of market forces, such as shortages. Specialty pharmacies constantly manage drug shortages within the generic marketplace for other classes of drugs as well as dramatic price increases for generic products. These market fluctuations occur because of an imbalance in the market. NASP is concerned that the Proposed Rule could cause a similar fluctuation within the immunosuppressant marketplace, which could have disastrous effects on the transplant patient if adequate blood levels of these medications are not maintained due to the inherent fluctuations in product availability across manufacturers.

The drugs listed above that are outside the incident to setting are predominantly distributed by specialty pharmacies, which means that the pharmacy and not the physician purchases the drug from the manufacturer and sells it to the Medicare program. The specialty pharmacist does NOT prescribe the drug, rather, the physician writes the prescription. As such, there is no financial connection between the entity that writes the prescription (provider/supplier) and the entity that “buys and bills” for the prescription. This is clearly different from the “incident to” drugs and the focus of the Payment Model, where the provider/supplier both prescribes the drug and “buys and bills” the drug. Given the disconnect between the financial incentive related to these drugs and the lack of agency’s reasoning for inclusion, NASP urges the agency to exclude these classes of drugs from the Payment Model should it go forward.

In light of the agency’s statements related to the purpose and scope of the Payment Model, NASP does not understand why CMS proposes to include these classes of drugs. The agency does not provide any further reasoning as to why “it is important” to include these drugs beyond the agency’s own statement. NASP believes the agency owes the beneficiaries it serves a justification for inclusion in light of the risk in gaps of care without meeting the purpose of the Payment Model.

B. The Payment Model’s Proposed Payments to Specialty Pharmacies will Adversely Impact Beneficiary Care

As stated earlier, CMS proposes to include the statutorily covered Part B drugs that are administered outside of the “incident to” setting. The agency also states that it will continue to reimburse the appropriate supply, dispensing and furnishing fees related to these therapies. Specifically, CMS states that “this phase (phase 1) of the model would not affect other payments that are associated with furnishing a drug such as the clotting factor furnishing fee, or supplying and dispensing fees that are authorized under section 1842(o) of the Act.”¹³ As such, during phase I of the Payment Model, CMS will reimburse the specialty pharmacy 102.5 percent of the therapy’s ASP, the corresponding supply, furnishing or dispense fee, and the proposed flat fee of \$16.80 per drug per day administered. These fees, however, do NOT take into account sequestration, which requires the reduction of Medicare payments by two percent such that the effective reimbursement for these drugs is 100.86 percent of ASP plus the flat fee of \$16.53 and the corresponding furnishing/dispensing/supply fee. This proposed fee structure is impractical given the level of clinical and educational services that the specialty pharmacy provides to the Medicare beneficiary that are subsumed and paid for by the current reimbursement methodology.

Specialty pharmacies provide a wide range of services for the Medicare beneficiary and the physician. For example, the expert services that specialty pharmacies provide drive adherence and persistency, proper management of medication dosing and side effects, and ensure appropriate medication use. The typical specialty pharmacy employs a highly educated clinically focused workforce to deliver its patient-centric model that is designed to provide a comprehensive and coordinated model of care for patients with chronic illnesses and complex medical conditions, achieve superior clinical and economic outcomes, and expedite patient access to care. All of these services are NOT separately reimbursed by the Medicare program, rather are “covered” by the current reimbursement methodology. For example, the average cost to fill a transplant therapy is \$200 per patient for their first six months of therapy due to administrative costs, patient education and medication and dose adjustments. These costs are similar for oral oncolytics due to the significant educational component and other administrative costs associated with disease management including coordinating enrollment into a CMS required Medication Therapy Management Program (MTM) under Medicare Part D.

The Payment Model’s proposed changes in reimbursement might be budget neutral overall, but the shifting of the dollars away from some therapies to other will have a dramatic impact on the many services that specialty pharmacies provide to Medicare beneficiaries. Simply stated, as a result of these changes, the independent specialty pharmacy will no longer be able to afford to provide them, which could have a dramatic impact on compliance and overall health outcomes.

¹³ 81 Fed. Reg. at 13239.

IV. Phase II of the Payment Model Does Not take Into Account the Costs or Value Provided by the Necessary Product Support Services Associated with Specialty Care

As stated above, specialty pharmacies perform a wide range of clinical services that often lead to better adherence and compliance that ultimately reduces overall healthcare costs and improved outcomes. It seems to NASP that the agency agrees and appreciates the value of these services when it states that

“this model’s goals are also consistent with the Administration’s broader strategy to encourage better care, smarter spending, and healthier people by paying providers and suppliers for what works, unlocking health care data, and finding new ways to coordinate and integrate care to improve quality.”¹⁴

Yet, NASP is disappointed that not one of the Phase 2 proposals includes thoughts on paying for care coordination, disease education, patient monitoring or other services that the agency mentions early in the preamble of the Proposed Rule.¹⁵ These programs have a demonstrated impact on reducing overall healthcare costs while improving outcomes. Equally frustrating is that the agency points to Medicare Part D as a model for implementing drug utilization tools that could be applicable to Part B, yet ignores the Medicare Part D Medication Therapy Management Programs, as mentioned above, and other disease education programs that exist within the Part D program that aid the plan with its drug utilization efforts. NASP urges CMS to be consistent with its language and its proposals to include and reimburse for the necessary corresponding product support services because as currently written the proposals within Phase 2 seem more geared at only reducing drug spend rather than managing appropriate utilization while maintaining appropriate access and improved beneficiary outcome.

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) program from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A REMS program may be required by the FDA as part of the approval of a new product, or for an approved product when new safety information arises. A REMS program is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use. Biopharmaceutical companies who develop and bring to market these new, innovative therapies for patients routinely partner only with specialty pharmacies to ensure that the requirements and conditions of these REMS programs are met. They do so relying on the specialty pharmacy’s high touch specialty service model, the expert therapy management services offered, the extensive patient education and counseling, the technical ability to capture the required data elements to support post-drug approval monitoring, and the comprehensive and coordinated model

¹⁴ 81 Fed. Reg. 13231.

¹⁵ Id.

of care to deliver these breakthrough therapies. Without specialty pharmacies, REMS programs could not be implemented effectively and according to FDA requirements. The Payment Model fails to mention these required programs and any other service model, and the value they bring to patients by affording access to therapies that might not otherwise be available. NASP looks forward to working with CMS to further explain these types of programs within the context of the broader services that specialty pharmacies provide for possible inclusion in Phase 2.

NASP does, however, appreciate and is encouraged by CMS' thoughts and statements related to the Competitive Acquisition Program (CAP). Specifically, CMS states that "we are interested in comments on whether there is a role for a CAP-like alternative to the ASP (buy and bill) process for obtaining drugs that are billed under Part B in the physician's office." NASP is very interested in engaging with CMS to discuss, as mentioned above, the ability of a specialty pharmacy to buy and bill traditional Part B drugs. That being said, any reincarnation of the CAP or development of a new program that removes the physician from the buy and bill process and shifts the drug fulfillment to the specialty pharmacy must also include provisions to reimburse for the many services provided by specialty pharmacies, such as REMS programs, in support of the chosen therapy.

There is precedent for increased service fees upon the reduction of drug revenue. For example, Congress increased the administration fees for IV therapies for 2004 and 2005 when the reimbursement methodology for incident-to drugs transitioned from Average Wholesale Price to Average Sales Price (ASP).¹⁶ Congress intended that this requirement would improve the appropriateness of Medicare's payments to physicians for drug administration services since the physician's revenue was dramatically reduced by the transition to ASP. Similarly, in exploring permitting specialty pharmacies to bill CMS for Medicare Part B drugs, the agency must simultaneously explore reimbursing specialty pharmacies for the services provided in support of the drug. Finally, the development of these programs naturally leads to the development of quality measures, which the Medicare program can then integrate into its Star Program.

V. Conclusion

NASP greatly appreciates the opportunity to comment on CMS' Proposed Rule and looks forward to continuing to work with CMS to ensure that Medicare beneficiaries have access to critical medications. Please contact NASP at (703) 842-0121 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

¹⁶ The Medicare Modernization Act required a two year transition adjustment that increased payments for drug administration services by 32 percent in 2004 and by 3 percent in 2005. Medicare Modernization Act § 303(a)(3).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Burt Zweigenhaft". The signature is written in a cursive, flowing style with some stylized flourishes.

Burt Zweigenhaft
President, NASP