January 11, 2010

By Electronic Delivery

Donald M. Berwick, M.D., MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4144-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes [CMS-4144-P]

Dear Dr. Berwick:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Proposed Rule entitled "Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes" (Proposed Rule),[1] particularly as it relates to appropriate dispensing of prescription drugs in long-term care (LTC) facilities. BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the world. BIO represents more than 1,100 biotechnology centers, academic institutions, state biotechnology centers, and related organizations in the United States and in more than 30 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering and ensuring patient access to new and innovative therapies. Many of the therapies developed by biotechnology companies target conditions that primarily affect seniors. BIO has been a strong supporter of the Medicare Part D prescription drug benefit, and believes that the program has helped to increase patient access to critical therapies, as well as ensure that patients are able to receive and afford the treatments that best meet their needs. While we support CMS's efforts to eliminate

[1] 75 Fed. Reg. 71,190 (Nov. 22, 2010).

pharmaceutical waste under the Part D program, we question whether the proposed requirement of 7-day dispensing in the LTC setting is necessary and has been thoroughly evaluated for potential negative impacts on patient care. If CMS persists in implementing such a policy we have a number of suggestions to assist CMS in ensuring meaningful patient access in its refinement of this important program. As such, we provide below some comments regarding the Proposed Rule.

Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA–PD Plans (Proposed § 423.154)

BIO supports CMS's efforts to reduce pharmaceutical waste under Part D. Maximizing such waste reduction may not only save money for the Medicare program, but will also help prevent drug diversion and environmental contamination. However, the goal of reducing pharmaceutical waste must be balanced against the need to provide beneficiaries with access to medically necessary items and services, including prescription medications. Indeed, interrupting access to many pharmaceutical products may result in detrimental and costly health consequences. As such, BIO urges CMS to ensure that its waste reduction efforts do not interrupt patient care. To best reduce waste without harming patients, BIO recommends that CMS apply the proposed 7-day-or-less dispensing restriction only where such a restriction is not likely to interfere with patient care, while protecting beneficiary access to medically necessary drugs through the addition of several important exceptions.

The Dispensing Restriction Should Be Applied Based on Therapeutic Considerations

In the Proposed Rule, CMS proposes to require most pharmacies servicing long-term care (LTC) facilities to dispense medications to Part D enrollees in such facilities in "no greater than 7-day increments at a time."[2] However, CMS also proposes "initially limiting the requirement for 7-day-or-less dispensing to brand-name drugs". BIO believes that this proposed phase-in of the 7-day-or-less dispensing restriction does not reflect patient care needs. We urge CMS to apply this restriction based on the nature of the therapy, and not whether the therapy is brand name or generic. For example, some drugs and biologicals may require a longer time period in order to gauge tolerance or efficacy, and in those circumstances a partial fill may not be medically appropriate. If CMS does adopt the proposed policy, CMS must ensure that a beneficiary's physician deem any partial fills to be medically appropriate. This will better ensure that patient access is not unduly hindered, while at the same time maximizing potential waste reduction.

First and foremost, CMS's proposed phase-in is unnecessary from both an administrative and a medical perspective. In the Proposed Rule, CMS claims that "a transitional approach would ease the initial burden on nursing facility staff time and LTC pharmacy pharmacist staff

[2] 75 Fed. Reg. at 71,205.

time." However, CMS concedes that industry representatives "opined that a transitional approach was not necessary and that the additional labor . . . was being overestimated."[3] In addition, to the extent that any additional labor is required, CMS has proposed to permit dispensing fees to be adjusted accordingly.[4] Instead, we believe it would be more appropriate to apply any dispensing restrictions based on the therapy being dispensed. As CMS acknowledges in the Proposed Rule, there is a need to create certain exceptions from the application of the dispensing restriction to protect beneficiary access to certain drugs, such as those for which 7-day-or-less dispensing would be infeasible. These reasons for distinguishing among therapies are not limited to brand name drugs.

Even CMS's purported basis for initially limiting the dispensing restriction to brand-name drugs fails to demonstrate the necessity of this phased-in approach. To support its proposal, CMS cites "discussions with industry" that "75 percent to 80 percent of the cost of drug wastage arises from only 20 percent of the drugs" and that this "20 percent is made up exclusively of brand-name medications."[5] We request that CMS provide sources for these numbers before adopting a policy based on this information. Besides the validity of these numbers, there are other significant variables not given consideration, such as patient care and delivery system issues that may connect to this analysis. Absent consideration of these variables, we believe that the analysis is incomplete.

CMS should further consider the significant increase in delivery and administration costs to these LTC facilities with the 7-day-or-less dispensing restriction policy. The more transactions that must take place to facilitate the waste reduction concern, the more charges the LTC facilities may face from the pharmacies that deliver such services, which may offset any savings gained. To reduce to 7-day-or-less could balloon the rate and drive cost upward for these facilities, possibly impacting patient care.

Additional Exceptions Are Required to Protect Patients

In the Proposed Rule, CMS proposes to exempt from the 7-day-or-less dispensing requirement "those drugs that are difficult to dispense in a 7 day or less supply and drugs that are dispensed for acute illness."[6] The rationale given for these exclusions is that "requiring these types of drugs to be dispensed in 7-day-or-less increments could result in safety or efficacy concerns or could have the counterproductive effect of increasing drug waste." BIO applauds the creation of these exceptions and believes that they are important for ensuring patient access to those medications that "do not lend themselves to a 7-day-or-less supply." BIO believes,

[3] Id. (emphasis added).
[4] Id. at 71,208.
[5] Id. at 71,205.
[6] 75 Fed. Reg. 71,205.

however, that these exceptions do not go far enough in protecting patient safety, particularly among Medicare's most vulnerable populations.

First, BIO urges CMS to consider an additional exception from the 7-day-or-less dispensing restrictions for CMS's six "protected classes" of drugs and for other therapies that, if interrupted, could cause harm to patients. CMS created six "protected classes" that must be covered by Part D formularies to protect vulnerable Medicare beneficiaries. These protected classes include medications taken by patients who could suffer adverse and costly health consequences if their access to such drugs were restricted.[7] For instance, patients who are unable to refill prescriptions for antineoplastics – one such protected class – may experience reductions in the therapeutic levels of such drugs, thereby diminishing their effectiveness, and potentially leading to additional doctor visits, hospitalizations, and severe medical consequences. In addition, Social Security Act § 1860D-4(b)(3)(G) generally requires Part D formularies to cover all Part D drugs for which: (1) restricted access would have major or life-threatening clinical consequences for individuals who have a disease or disorder treated by the drugs, and (2) there is a significant clinical need for individuals who have a disease or disorder to have access to such drugs.[8] Because the 7-day-or-less dispensing policy could have detrimental effects with respect to drugs in these categories, BIO urges CMS to create an additional exception from the proposed dispensing restrictions for these six "protected classes" and any other categories of drugs exempted by CMS under 1860D-4(b)(3)(G).

Second, BIO asks CMS to create an exception for circumstances in which a beneficiary's physician overrides a partial fill for a particular patient based on a showing of medical necessity. In some cases, partial fills may be medically inappropriate. For example, certain medications may require a longer period of time in order to gauge tolerance or efficacy. In other situations, a shorter course of medication may simply not be effective. For example, if a patient does not refill a partial fill of an antibiotic, his or her infection could resurface, with much greater clinical and cost consequences. Where a physician knows that a particular patient's circumstance necessitates an initial fill or refill of more than seven days worth of prescriptions for these or other reasons, BIO believes that the physician should be able to selectively override the 7-day-or-less dispensing restriction set forth in the Proposed Rule.

Finally, CMS should consider additional exemptions, such as for injectables that are prescribed based on therapeutic regimens that are longer than 7-days, and for the treatment of chronic conditions that may require long-term therapy. Injectable drugs that are prescribed for duration greater than 7-days should be exempted from this policy to ensure that the patient's

[7]The six "protected classes" include: Antidepressants, Antipsychotics, Anticonvulsants, Immunosupressants (drugs to prevent the rejection of organ transplants), Antiretrovirals (drugs that combat the progression of HIV and AIDS), and Antineoplastics (cancer fighting agents). Centers for Medicare & Medicaid Services, Medicare Prescription Drug Manual, Chapter 6 – Part D Drugs and Formulary Requirements § 30.2.5 (Revised effective March 1, 2010).

[8] Social Security Act § 1860D-4(b)(3)(G), 42 U.S.C. § 1395w-104(b)(3)(G).

condition or therapeutic response is not negatively impacted. In addition, if the patient has been diagnosed with a chronic condition that requires long-term therapy, CMS should consider limiting the 7-day-or-less requirement to the initial period to ensure that the patient is showing a positive therapeutic response, or is tolerating the therapy without any side effects or complications. Subsequently, if the patient is responding well and without adverse reactions, the restriction should be lifted at least until the next physician's review of the case, or if the condition is resolved at the end of the prescription.

Conclusion

BIO appreciates the opportunity to comment on the Proposed Rule. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact me at 202-962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/

Laurel L. Todd
Managing Director
Reimbursement and Health Policy