BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule [CMS-1385-P]

Dear Acting Deputy Administrator Kuhn:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule regarding revisions to payment policies under the physician fee schedule for calendar year 2008 and other changes to payment policies under Part B (the "Proposed Rule").[1] BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations. 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 new treatments and ensuring patient access to them. Accordingly, we continue to be concerned about the impact of Medicare's reimbursement rates and payment policies on access to drugs and biologicals, particularly in light of the deep cut in the conversion factor that is projected for 2008. If Medicare does not compensate providers appropriately for their acquisition and administration costs, Medicare beneficiaries

[1] 72 Fed. Reg. 38,122 (July 12, 2007).

may be denied access to essential drugs and biologicals. If physicians and hospitals stop providing state-of-the-art therapies to their patients as a result, manufacturers could be discouraged from developing new therapies. BIO urges CMS to protect beneficiary access to important drug and biological therapies by ensuring that physicians are appropriately reimbursed for all of the services associated with providing these therapies. It is with these important goals in mind that our comments:

- Urge CMS to continue pre-administration payments for intravenous immune globulin (IVIG) and implement an additional payment to ensure beneficiary access to this critical biological therapy;
- Seek further clarity regarding the definition of a bundled arrangement under the average sales price (ASP) methodology;
- Support CMS' proposal regarding the clotting factor furnishing fee;
- Urge CMS to place limits on its substitution of widely available market price (WAMP) or average manufacturer price (AMP) for ASP;
- Urge CMS to allow physicians to withdraw from the Competitive Acquisition Program (CAP) under exigent circumstances at any time and to eliminate the 14-day physician billing requirement for CAP drugs;
- State that the agency's proposal to allow CAP vendors to repackage biologicals into prefilled syringes violates food and drug law and risks patient safety and should be withdrawn;
- Suggest improvements to the current system of setting payment rates for innovative clinical diagnostic laboratory tests;
- Support CMS' proposal to reimburse all end-stage renal disease (ESRD) drugs and biologicals at ASP plus six percent;
- Support CMS' proposal to provide Medicare coverage for vaccines in Comprehensive Outpatient Rehabilitation Facilities (CORFs);
- Urge CMS to modify its list of accepted compendia used to determine medically-accepted indications for drugs and biologicals used in anticancer chemotherapeutic regimens by recognizing DrugPoints® as a successor publication and adding the National Comprehensive Cancer Network's Drugs and Biologics Compendium™;

- Encourage CMS to finalize quality measurements that are scientifically valid, consensus-based and that minimize physician burden, and ask the agency to take the lead on developing and implementing care coordination quality measurements;
- Encourage the agency to adopt the proposed quality measures for the Physician Quality Reporting Initiative (PQRI) related to influenza and pneumonia vaccination; and
- Urge CMS to do anything within its power to mitigate the substantial cuts in the conversion factor and to ensure Medicare beneficiaries continue to have access to high quality care.

These issues are discussed in depth below.

I. CODING—PAYMENT FOR IVIG ADD-ON CODE – BIO urges CMS to continue pre-administration payments for IVIG and implement an additional payment to ensure beneficiary access to this critical biological therapy.

BIO appreciates that CMS continues to propose polices to help ensure that Medicare beneficiaries can access IVIG in the physician's office setting. BIO has been very concerned about Medicare beneficiary access to standard and specialty IVIG over the past few years as a result of the changes in the Medicare payment methodologies for drugs and biologicals. As stated in the Proposed Rule, CMS recently created four new codes for liquid non-lyophilized IVIG for use effective July 1, 2007.[2] BIO agrees with CMS that these new codes should improve beneficiary access to IVIG.

Additionally, BIO is pleased that CMS proposes to continue payment for pre-administration related services for IVIG. As in 2007, physicians will be able to bill G0332 to receive pre-administration payments. We note that G0332 is not included in Addendum B, however, and ask the agency to add it in the Final Rule. We are concerned that CMS only proposes to continue payment for G0332 through calendar year 2008. Before payment for pre-administration related services is

[2] Id. at 38,146.

discontinued in the future, we ask the agency to ensure that beneficiary access to IVIG will not be compromised.

BIO also believes that CMS should establish an additional payment in order to ensure providers are able to purchase IVIG. One model that has worked in the past is the add-on payment for blood clotting factor. This model is based on a January 2003 GAO report that recommended that CMS establish a separate payment for the cost of delivering clotting factor to Medicare beneficiaries.[3] Then Congress granted such authority to the Secretary in order to preserve patient access to blood clotting factor. BIO believes that the IVIG payment is also insufficient and requires an additional payment to help deliver the therapy. The HHS Office of the Inspector General in its April 2007 study of the IVIG market, demonstrates that only 59 percent of IVIG sales to physicians by the three largest distributors occurred at prices below the Medicare payment amounts at the time of the study.[4] One would expect this percentage to further decline when taking into account smaller distributors. Two other recently published reports also point to Medicare reimbursement as continuing to be a barrier to patient access to IVIG.[5]

Therefore, BIO asks that CMS treat IVIG similar to another blood-plasma derived therapy – blood clotting factor – and provide an additional payment to address this continued therapy reimbursement shortfall. This measure combined with the positive steps that CMS has undertaken is an important first step toward rectifying the patient access difficulties surrounding IVIG.

II. ASP ISSUES

A. BIO seeks further clarity regarding the definition of bundled arrangement under the ASP methodology.

In the Proposed Rule, CMS proposes to revise the methodology for determining the ASP for Part B drugs by defining bundled arrangements and

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[3] General Accounting Office, Medicare: Payments for Blood Clotting Factor Exceeds Providers' Acquisition Cost, January, 2003, GAO-03-184.
[4] Id.
[5] Id.

requiring that drug manufacturers allocate bundled price concessions proportionately to the dollar value of units of each drug sold under the bundled arrangement when reporting ASPs. BIO appreciates that CMS has decided to use the rulemaking process to engage stakeholders on the appropriate definition and methodology for addressing bundled arrangements for the purpose of determining ASP, and urges CMS to continue to use rulemaking to make changes to ASP. BIO supports ASP because it is a market-based reimbursement methodology.

CMS explains that its proposal on bundling is in response to the Medicare Payment Advisory Commission's (MedPAC) January 2007 report to Congress. The Proposed Rule accurately notes that MedPAC recommended that, "the goal should be to ensure that ASP reflects the average transaction price for drugs."[6] CMS also correctly points out that MedPAC advised that the reporting requirements for allocating discounts should be clear and capable of being implemented in a timely fashion by manufacturers. While MedPAC opined that application of the Medicaid bundling policy used to determine AMP, with some adjustments, might be simpler to administer than an alternative that was considered, BIO notes that MedPAC did not explicitly recommend that the Medicaid bundling rule or any other specific methodology be applied to the ASP calculations.

BIO believes that the bundling definition that appears in the AMP Final Rule that CMS has proposed to apply to ASP would impose a significant administrative burden on manufacturers in part because CMS has expanded the definition of "bundled arrangements" in such a way that underscores the need for clarity and predictability. As CMS' own statement in the Preamble recognizes, "there is a potential for great variation in the structure of bundled arrangements and in the characteristics of products included in those arrangements."[7] While BIO appreciates that CMS has proposed specific guidance regarding the treatment of bundled price concessions in an effort to ensure greater consistency in ASP reporting, we believe it is critical that CMS provide additional clarity to manufacturers on the scope of CMS's new definition of a "bundled arrangement."

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[6] 72 Fed Reg at 38,150
[7] Id. at 38,151

BIO considers several aspects of the proposed "bundled arrangement" definition particularly troubling. CMS proposes to define this term for ASP calculation purposes to be an arrangement under which the rebate, discount, or other price concession is conditioned upon "the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), or where the resulting discounts or other price concessions are greater than those that would have been available had the bundled drugs or biologicals been purchased separately or outside of the bundled arrangement."[8] BIO is concerned that this language may be construed too broadly in certain instances.

BIO also urges CMS to clarify whether the proposed definition of a "bundled arrangement" could be interpreted to mean a portion of a contract, where the terms relating to some drugs under the contract do not meet the proposed definition. For example, a "bundled arrangement" may be part of a larger contract that includes other products that are priced with no conditions or contingencies with other products. BIO believes that these other products should not be included in the bundled arrangement, because the contract contains no price concessions for those drugs which are "conditioned on the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement."[9] Requiring reallocation of these discounts would not accurately reflect the prices available in the marketplace and would distort the ASPs of all drugs under the contract. Accordingly, we recommend that CMS clarify that these drugs are not considered part of the bundled arrangement for purposes of ASP calculation.

BIO notes that some contracts may offer a customer both contingent and non-contingent discounts on the same products. In some instances, the customer may not meet the volume purchase or other performance requirement for the contingent discounts under the contract. BIO requests that CMS provide specific guidance in its final rule regarding whether a contract should be treated as a bundled arrangement, and the discounts under the arrangement reallocated, where

[8] Id. at 38,226.
[9] Id. (proposed 42 C.F.R. § 414.802).

the customer has not met the performance or purchase requirements for the contingent discount. In addition, CMS should provide guidance on the allocation of a non-contingent discount in those situations where a contingency does exist (e.g., a non-contingent discount on a product that is also subject to an additional discount that is contingent on a volume purchase or other performance requirement). This additional clarity will help to ensure that manufacturers employ a uniform approach for reallocating discounts under a bundled arrangement.

However CMS proceeds to define "bundled arrangement," BIO urges the agency to define it based upon free market principles that will cause the least disruption as possible in the marketplace. In proposing to define this term for purposes of reporting ASP, CMS makes clear that it is seeking "to establish a method for treating bundled price concessions for purposes of ASP that is consistent with the method proposed for AMP calculations while addressing existing program differences."[10] BIO is concerned by the expanded definition of bundled arrangement in the Proposed Rule, and urges CMS to provide additional clarity to manufacturers to address these concerns.

Given that provider payment rates depend largely on reported ASPs, BIO believes it is essential that the methodology used to determine ASP accurately incorporates the costs to a provider or supplier for our therapies. Moreover, the ASP calculation and reporting requirements should be clearly articulated in light of the current enforcement environment because manufacturers may be subject to significant penalties for the submission of incorrect ASP data. BIO supports clear guidelines such that manufacturers can carry out their reporting obligations in compliance with all applicable laws and regulations. Predictability and transparency are essential for compliance reasons and are particularly important if CMS wants to promote consistency in the treatment of bundled price concessions for purposes of ASP reporting.

[10] Id.

B. BIO supports increasing the clotting factor furnishing fee.

CMS has proposed, consistent with the SSA,[11] to increase the clotting factor furnishing fee by the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending in June 2007.[12] BIO supports this proposal and requests that CMS publish the updated furnishing fee in the final rule once the CPI data becomes available.

Currently, the clotting factor furnishing fee is updated annually and is equal to the fee for the previous year increased by the percentage increase in the CPI for medical care for the 12-month period ending with June of the previous year.[13] Because the annual June CPI information is not available at the time the proposed physician fee schedule is published, CMS proposes to remove this annual update from the rulemaking process and issue future updates through program instructions instead. BIO agrees with this process as long as CMS continues to use the current methodology. Should methodological changes be made in the future, however, CMS should go through the formal rulemaking process.

C. CMS should place limits on its substitution of WAMP or AMP for ASP to set reimbursement.

The Medicare statute allows the Secretary to substitute the WAMP or AMP for ASP if ASP exceeds WAMP or AMP by a certain percentage.[14] The legislative history of this statutory provision clarifies that Congress intended for the Secretary to provide "a number of procedural and substantive safeguards to ensure the reliability and validity of the data" when deciding to substitute WAMP or AMP for ASP.[15] The proposed regulation states, "If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2008, the payment limit

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[11] SSA § 1842(o)(5)(C).
[12] 72 Fed. Reg. at 38,152.
[13] SSA § 1842(o)(5)(C).
[14] See SSA § 1847A(d)(3)(A).
[15] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, H.R. Rep. No. 108-391, at 592 (noting that the safeguards include "notice and comment rulemaking, identification of the specific sources of information used to make [a determination to use WAMP instead of ASP], and explanations of the methodology and criteria for selecting such sources").

in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price."[16] BIO urges the agency to provide for the procedural and substantive safeguards envisioned by Congress to ensure the reliability of the data. We appreciate the agency's statements that it will proceed cautiously in this area and seek stakeholder input, particularly from manufacturers impacted by potential price substitutions.

BIO urges CMS to consider the recent changes to the AMP methodology, as well as proposed changes to the ASP calculation, in deciding what threshold to put in place for 2008. Five percent might be insufficient in light of the recent requirement that sales to physician clinics and other purchasers be included in calculating AMP and the likely difference in implementation dates of any re-allocation requirements for AMP and ASP. These changes could affect the relationship between AMP and ASP.

Further, BIO believes that the proposed regulation's language is inconsistent with section 1847A(d)(3)(A) of the SSA that specifies that the Secretary "may" disregard ASP where the ASP exceeds WAMP or AMP by a certain threshold. Accordingly, we ask that this regulation be clarified to specify that the Secretary has discretion as to whether to substitute WAMP or AMP for ASP. Moreover, BIO urges CMS to obtain public input prior to determining whether to make such a substitution given that many drugs and biologicals have unique market dynamics that could skew these studies. Without obtaining all relevant information, especially in light of the recent changes to the AMP methodology, CMS may reduce payment rates where it should not, ultimately harming patient access to important therapies.

Consequently, BIO specifically requests that CMS revise its regulatory text to modify 42 C.F.R. § 414.904(d)(3) to read: "If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2008, the Secretary may, after providing notice and an opportunity to comment, revise the payment limit in

[16] Proposed 42 CFR § 414.904(d)(3); 72 Fed. Reg. at 38,226.

the quarter following the transmittal of this information to the Secretary to the lesser of the widely available market price or 103 percent of the average manufacturer price." This proposed language is consistent with CMS' statement that it will "proceed cautiously in this area and provide stakeholders, particularly manufacturers of drugs impacted by potential price substitutions with adequate notice of our intentions regarding such, including the opportunity to provide input with regard to the processes for substituting the WAMP or the AMP for the ASP."[17] It is imperative that CMS provide the public an opportunity to comment on any substitution of ASP before the agency proceeds. Moreover, in order for the public to comment meaningfully, BIO urges CMS to provide a thorough description of the sources of information used in the OIG's study, the methodology and criteria for selecting these sources, a description of any surveys and how they were conducted, and CMS' plans to use the data.

III. CAP ISSUES

A. The Competitive Acquisition Program (CAP) should promote beneficiary access to innovative therapies while minimizing administrative burdens on physicians.

In addition to offering all physicians broad access to appropriate drugs and biologicals, CAP must not impose excessive burdens on participating physicians and the Medicare beneficiaries they treat. Accordingly, BIO agrees with CMS that the approved CAP vendor may not collect any coinsurance from a Medicare beneficiary or his or her supplemental insurer unless it has verified that the drug was administered. BIO also supports CMS' definition of promptly – two weeks – as the time by which the CAP vendor must refund any payment for the cost sharing mistakenly collected by the CAP vendor to the Medicare beneficiary.[18] In addition, BIO suggests that the agency require the CAP vendor to pay a penalty above the amount owed if it does not refund the cost sharing within the two-week time frame.

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[17] 72 Fed. Reg. at 38,153.
[18] Id. at 38,156.

BIO also urges CMS to withdraw the current requirement that physicians who enroll in CAP must file a claim within 14 calendar days of the drug administration. BIO believes that as a result of certain provisions of the Tax Relief Health Care Act (TRHCA), this requirement is no longer necessary and now only serves to hamper physician enrollment.[19] Specifically, CMS must now pay for drugs and biologicals upon receipt of a claim for those products covered under the CAP and does not need to wait for a physician claim. TRHCA also requires CMS to establish a post-payment review process to assure that payment is made for a drug only if the drug has been administered to a beneficiary.[20] Prior to TRHCA, a CAP vendor could not get paid until the physician's drug administration claim was matched (e.g., a pre-payment review) with the claim for the drug submitted by the CAP vendor.

In the CAP final rule,[21] CMS made clear that the basis of the 14-day billing requirement was to allow the CAP vendor to be paid promptly for drugs it had shipped. Because TRHCA removed the claims match predicate to the CAP vendor's payment, we believe that requiring physicians to file a claim within 14 days is no longer necessary. To make the program more workable for physician practices that do not customarily submit bills in this timeframe, we recommend that CMS withdraw this requirement for physicians electing CAP. This step should also make the program more attractive to prospective CAP physicians.

B. BIO urges CMS to extend and simplify the process for physician withdrawal from the CAP under exigent circumstances.

CMS allows physicians to withdraw from the CAP outside of the annual selection process if the CAP vendor ceases participation in the CAP; the physician leaves a group practice participating in CAP; the participating CAP physician relocates to another competitive acquisition area; or for other exigent circumstances as defined by CMS.[22] BIO appreciates that CMS proposes to define

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[19] TRHCA § 108(a).
[20] Id.
[21] 70 Fed. Reg. 39,021, 39,050 (July 6, 2005).
[22] 42 C.F.R. § 414.908(a)(2).

exigent circumstances but is concerned that the process and timeframes are not clear or workable.

CMS would give a physician only 30 days to submit a written request to terminate his or her participation in the CAP. CMS gives three examples to illustrate an exigent circumstance; however, for each example 30 days is insufficient time for most physicians to recognize their continued participation in CAP is problematic. CMS' examples of exigent circumstances include a physician's inability to update his or her billing system, a practice's reliance on misleading information, or a demonstration of financial hardship. In each of these circumstances, 30 days is an insufficient amount of time for physicians to accurately assess that CAP participation causes hardship, which seems unreasonable in light of the fact that physicians are committing to the program for a full year. The proposed time frame of 30 days does not give physicians enough time to fully assess their financial circumstance or upgrade their billing systems. Therefore, we propose that CMS place no time limitation on a physician's ability to request termination from the CAP for exigent circumstances. Instead the issue of timing should be examined as one of several elements when adjudicating the request.

CMS proposes that it will review the designated carrier's recommendation and make the ultimate decision regarding the physician's request to withdraw from the CAP within two business days of receiving the request. BIO appreciates that CMS will make a quick determination, however, we urge CMS to further clarify precisely how it will make this determination. For example, what information, if any, will CMS examine beyond the designated carrier's recommendation, how much deference is the agency affording the designated carrier, and who within the agency will make the final decision. BIO believes that the process for withdrawing from the CAP should be as simple and straightforward as possible for physicians.

C. CMS' proposal to allow CAP vendors to repackage biologicals into prefilled syringes violates food and drug law and risks patient safety and should be withdrawn.

CMS requests comment on the feasibility of allowing CAP vendors to repackage certain biologicals from sterile single dose vials into prefilled syringes.[23] Even though CMS believes that a CAP vendor may be able to repackage certain biologicals and still comply with FDA law, we believe that this activity will be done on such a scale as to violate FDA law regarding manufacturing and compounding pharmacy requirements. Additionally, this activity could put patients at substantial risk. Section 1847B(b)(4)(C)(ii) of the SSA explicitly states, "Nothing in this subparagraph shall be construed to relieve or exempt any contractor from the provisions of the Federal Food, Drug, and Cosmetic Act that relate to the wholesale distribution of prescription drugs." CMS' proposal violates the Federal Food, Drug and Cosmetic Act (FFDCA) and must be withdrawn.

Specifically, CMS states that it is considering allowing a CAP vendor to provide to physicians "repackaged" drugs in prefilled syringes through the CAP program. Under this proposal, a physician would order a prefilled syringe through a CAP vendor that would be a "pharmacy or have access to pharmacy services . . . for the small scale preparation of sterile drug products in response to a specific prescription order for a specific patient."[24] The proposal goes on to assert that it is also seeking comments on whether a CAP vendor may "supply bevacizumab . . . if it is repackaged in a patient-specific dose."[25]

This proposal – seemingly designed to allow a CAP vendor to supply bevacizumab in a dosage form different from that approved by FDA – runs headlong into firmly established and well-enforced legal requirements for making changes to approved drug products. It seems that CMS is considering allowing CAP vendors to create unapproved new drug products and receive reimbursement for those products under Medicare.

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[23] 72 Fed. Reg. at 38,159.
[24] Id.
[25] Id.

FDA has long taken the position that certain changes to an approved new drug will create a wholly different drug product that requires separate and distinct review and approval by the agency, however. FDA has identified numerous factors that trigger the need for submission of a new drug application, including:

- use of a new substance that composes the drug, including a new "carrier" such as a prefilled syringe rather than a vial or intravenous bag;
- use of a new dosage, or method or duration of administration of the drug; and,
- use of the drug to treat a different disease or to affect another structure or function of the body.[26]

And, when the holder of an approved new drug application proposes to change the way a drug is delivered, FDA regulations specify that "changes in the type (e.g. . . . vial to syringe) . . . of a packaging component" requires pre-approval of a supplemental new drug application by the agency.[27]

FDA has a long history of regulating repackaging activity. In the mid-1980s, FDA brought suit to stop a repackaging operation in which a large drug manufacturer was reconstituting, repackaging, and distributing approved drug products. The repackaging operation was "designed to transform [drug] powders and concentrates on a large scale into dosage packages suitable for immediate use by health-care providers, who then administer the drugs without further reconstitution or dilution."[28] The court held that these actions – even though they were being conducted in a manner similar to the FDA approved instructions for reconstituting the drugs – created new drugs that each required a separate and distinct approval by FDA.[29]

Here, CMS seems to be suggesting that the CAP vendor can do just what FDA prohibits manufacturers from doing – take drugs approved for administration through one method (vials and intravenous injection) and change the route of

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[26] See 21 § C.F.R 310.3(h).
[27] 21 C.F.R § 314.70(b)(2)(vi).
[28] United States v. Baxter Healthcare Corp., 901 F.2d 1401, 1403 (7th Cir. 1990).
[29] Id.

administration to another, a prefilled syringe. Although CMS states that it is "not contemplating manufacturing of drug products"[30] under this program, FDA regulations and enforcement history make clear that, were CMS to adopt the proposal, it would be doing exactly that – allowing vendors and their pharmacies to manufacture unapproved new drug products.

Even if the "repackaging" proposal itself were not contrary to FDA regulations and policies, certainly a proposal that pharmacies compound drugs on a large scale (i.e. for hundreds of Medicare beneficiaries) would be enough to draw FDA attention. Pharmacy compounding generally is described as the process by which a pharmacist combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Such drugs typically are created in the absence of a commercially available drug which would serve a similar purpose.[31] FDA regulates large-scale pharmacy compounding because it represents drug manufacturing, not the traditional practice of pharmacy. For example, FDA has issued warning letters to compounding pharmacies stating that because bevacizumab has no approved indications for uses in the eye, repacking bevacizumab into syringes for subsequent promotion and sale violates FDA law because the pharmacist was distributing an unapproved new drug.[32] Each step in the manufacture and processing of a new drug, from handling of raw ingredients to final packaging, must be approved by the FDA whether it is done by the original manufacturer or by a subsequent handler or repackager of the product.[33]

Because pharmacists are not exempt from this requirement, processing and repackaging of approved drugs is beyond the practice of pharmacy and is thus subject to FDA's pre-market approval requirements. Therefore, CMS cannot mitigate its proposal by suggesting that it would only allow access to limited pharmacy services that would operate on a small scale as clearly the intent of the proposal is for large-scale distribution. Nor can CMS propose a program where compounded drug products would be made available through Medicare where

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[30] 72 Fed. Reg. at 38,159.
[31] See Thompson v. Western States Med. Ctr., 535 U.S. 357 (2002).
[32] http://www.fda.gov/foi/warning_letters/g6147d.htm.
[33] Compliance Policy Guide, Sec. 446.100, *Regulatory Action Regarding Approved New Drugs and Antibiotic Drug Products Subjected to Additional Processing or other Manipulations* (CPG 7132c.06).

other approved drug products are commercially available that serve the same or similar purposes. BIO urges CMS to carefully consider the legal requirements of drug and biological manufacturing and distribution as it considers this policy.

Perhaps even more essential, CMS should consider the safety of Medicare beneficiaries as it considers this policy. The FDA's Compliance Policy Guide states, "the FDA has an even greater concern about the manipulation of approved sterile drug products, especially when the sterile container is opened or otherwise entered to conduct manipulations such as dissolving, diluting or aliquoting, refilling, resterilizing, or repackaging in new containers. The moment a sterile container is opened and manipulated, a quality standard (sterility) is destroyed and previous studies supporting the standard(s) are compromised and are no longer valid. These quality standards that include product stability and sterility must be restored."[34] BIO urges CMS to withdraw its proposal regarding prefilled syringes because it violates the law and risks the safety of Medicare beneficiaries.

IV. CLINICAL LABORATORY ISSUES

A. The current system of setting payment rates for new clinical diagnostic laboratory tests must be improved dramatically in order to realize the promise of personalized medicine.

In order to realize the promise of personalized medicine, targeted diagnostics must be seen as the entryway and must be evaluated and reimbursed in a new manner. Many of the newer lab tests, and even more of those in development, represent an entirely new generation of diagnostics that can predict who is likely to develop certain cancers and other diseases, whether and how they will respond to particular therapeutics, what dosage of a particular drug is optimum for the individual, how combinations of drugs will be metabolized by people with particular genetic traits, and the likelihood of recurrence of certain diseases. Furthermore, many other novel molecular diagnostics are being developed for disease sub-typing, disease prognosis, and treatment side-effects. These diagnostics will facilitate treatment that is far more tailored to individual

[34] Id.

characteristics than has ever been possible before and will save money and lives by avoiding futile or even dangerous therapies while helping to ensure the use of the most appropriate treatment. Indeed, diagnostic tests increasingly will be inextricably linked with certain therapeutics, with the diagnostic test result being a prerequisite to determine whether to prescribe the therapeutic at all or to establish the precise treatment regimen.

BIO is concerned, however, that maintaining the current reimbursement system will not provide sufficient incentives to encourage these innovations. Currently, diagnostic tests are reimbursed by either "crosswalking" the test into a current code or creating a new code for the test and allowing the carriers to "gap fill" or establish their own prices for the new code for a period of time until a national rate is calculated. Although neither methodology is market-based, slowing the pace of innovation, BIO looks forward to working with CMS to further refine the crosswalking and gapfilling methodologies to create a transparent and predictable system that will stimulate and reward innovation and take into account the value of new tests.

B. BIO generally supports the proposed reconsideration process.

Currently, diagnostic manufacturers do not have a mechanism to appeal either the basis for payment or the amount of payment for diagnostic tests paid under the clinical lab fee schedule. BIO appreciates that CMS is proposing a detailed reconsideration process for manufacturers to use to switch the basis of payment or the amount of the payment under both the crosswalking and gapfilling methodologies. CMS proposes to receive public comments for 60 days after making a determination of either the basis for payment or the amount of payment and then to allow those who submitted comments to present at its annual meeting regarding the clinical lab fee schedule.[35] BIO agrees that the agency should provide a public forum for stakeholder comments but asks that the agency allow all interested stakeholders the opportunity to present at the public hearing, not just those who submitted comments within the 60 day comment period. Further, BIO

[35] Proposed 42 CFR § 414.509; 72 Fed. Reg. at 38,225.

asks that CMS clearly articulate the agency's reasons for granting or denying a request to reconsider a determination.

C. BIO urges CMS to provide greater detail regarding the process used to determine payments under the crosswalking methodology.

As stated above, BIO appreciates the proposed reconsideration process and urges the agency to further clarify the reasoning behind certain agency decisions. Similarly, BIO requests that CMS provide greater detail regarding the agency's decisionmaking process regarding the payment amount when a new test is crosswalked to an existing test or tests. The Proposed Rule states that CMS will make the decision regarding the amount of payment, and it is not subject to further reconsideration.[36] BIO urges the agency to provide greater detail and clarity regarding the payment decisionmaking process.

D. The gapfilling process does not stimulate innovation.

Developing and bringing to market this new generation of diagnostic tests typically is far more costly and complex than the traditional lab test. And even under CMS' gapfilling methodology, aimed at new tests for which there is no comparable, existing test, BIO is concerned that pricing variations among carriers may be so great, and so unpredictable, that innovation will be stifled and beneficiary access to these tests impeded. We also are concerned that setting a national payment amount when the market for the tests is not yet well-established and little claims experience is available will lead to inappropriate reimbursement and little opportunity for adjustment even if the pricing later is acknowledged to have been set too low. In addition, because many of these new tests are proprietary and may be offered and performed by only one lab in the country, the gapfilled price established by the carrier serving that lab becomes a *de facto* national price, and if it is insufficient, it may not be economically feasible for the lab to offer the test at all.

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[36] 72 Fed. Reg. at 38,162.

BIO urges CMS to engage in discussions, both internally and with external stakeholders, to explore the research, therapeutic, and economic environments in which these new generation diagnostic tests are developed and to ensure that Medicare's payment policies take into consideration the investment of human and capital resources that go into these diagnostics, as well as the tremendous potential benefits, in terms of cost savings, clinical outcomes, and quality of life for Medicare beneficiaries. In the short term, we also ask that CMS seek input from interested parties in this arena regarding the appropriate guidance and criteria to provide to contractors that are pricing these novel lab tests. By ensuring appropriate value recognition of molecular diagnostic tests, the agency will create financial stability and attractiveness for the industry, further facilitating continued investment and development of these diagnostics. This will go a long way towards realizing the promise of personalized medicine.

V. ESRD PROVISIONS – BIO supports CMS' decision to continue to reimburse all ESRD drugs and biologicals at ASP plus six percent.

In the Proposed Rule, CMS does not propose any changes to reimbursement for separately billable ESRD drugs and biologicals at ASP plus six percent.[37] BIO continues to support using the ASP plus six percent methodology for separately billable drugs when billed by freestanding or hospital-based ESRD facilities. ASP-based reimbursement is the best option available under the statute, and it is more accurate and easier to administer than updating a prior year's acquisition cost data.

VI. PAYMENT FOR CORF SERVICES – BIO supports CMS' proposal to permit coverage of vaccines in the CORF setting.

BIO strongly supports CMS' proposal to cover the administration of pneumococcal, influenza, and hepatitis B vaccines to CORF patients. Although such vaccines have traditionally fallen outside the scope of CORF services, CMS' proposal to revise the conditions of participation at §485.51(a) to permit CORFs to provide to their patients these important vaccines in addition to CORF services is an important means of ensuring that all Medicare beneficiaries have increased

[37] Id. at 38,163.

access to vaccinations, ensuring they receive high quality health care. Increasing the settings in which Medicare beneficiaries can receive immunizations will improve health outcomes.

VII. DRUG COMPENDIA

A. BIO urges CMS to modify its list of accepted compendia by recognizing DrugPoints® as a successor publication and adding the National Comprehensive Cancer Network's Drugs and Biologics Compendium™ by the end of the year.

BIO supports CMS' proposal to create an annual process for updating the list of compendia used to determine medically-accepted indications for drugs and biologicals used in anticancer chemotherapeutic regimens. We also believe that more immediate action is warranted, however, and urge CMS to complete its current process and modify its list of accepted compendia by recognizing DrugPoints® as a successor publication and adding the National Comprehensive Cancer Network's Drugs and Biologics Compendium™ by the end of the year. BIO's members invest millions of dollars each year researching potential cancer treatments, and it is crucial for the patients we serve to have timely access to our therapies as they battle these deadly diseases. Although we believe it is important for CMS to implement an annual process to evaluate applicants in the future, we also believe it is critical for patient care for the agency to act promptly to add those publications that already have applied.

The practice of medicine constantly evolves through the incorporation of new clinical discoveries into clinical care. In oncology, for example, the standard of care advances approximately every six months, if not sooner, as clinical research discovers effective new treatment regimens that extend and improve quality of life. Many of these new treatment options involve the use of drugs and biologicals for indications not initially approved by the FDA. New clinical uses of FDA-approved therapies offer patients and physicians new hope and greater choice in fighting illness and can be particularly important for patients with advanced

stages of cancer.[38] As scientific advances are publicized through peer reviewed publications, scientific compendia often incorporate this information before it appears on the FDA label. Thus, compendia are an important resource for physicians when determining the most appropriate treatment regimen for their Medicare beneficiaries.[39]

Congress also recognized the importance of scientific compendia in expanding treatment options for cancer patients. In 1993, it amended the SSA[40] to add to the definition of drug for purposes of coverage, "any drug or biological used in an anticancer chemotherapeutic regimen for a medically accepted indication."[41] The statute further defines medically accepted indication to include:

> any use which has been approved by the Food and Drug administration for the drug, and includes another use of the drug if—(i) the drug has been approved by the Food and Drug Administration; and (ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia.[42]

Although Congress clearly intended Medicare contractors to use at least three compendia to allow Medicare beneficiaries access to state-of-the-art cancer care, only one of these listed compendia – Amercian Hospital Formulary Service-

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[38] Off-Label Use of Anticancer Therapies: Physician Prescribing Trends and the Impact of Payer Coverage Policy, Sept. 2005, at 5, available at http://www.bio.org/speeches/pubs/CovanceReport.pdf.
[39] Id. at 6.
[40] Section 13553(b) of the Omnibus Budget Reconciliation Act of 1993 entitled, "Uniform Coverage of 'Off-Label' Anticancer Drugs."
[41] SSA § 1861(t)(2)(A).
[42] SSA § 1861(t)(2)(B).

Drug Information (AHFS) – is available today. The American Medical Association Drug Evaluations (AMA-DE) no longer is in publication, and United States Pharmacopoeia-Drug Information (USP-DI) now is published by Thomson Micromedex® under the name DrugPoints®. Fortunately, Congress recognized that compendia might change over time and included in the statute a provision permitting the Secretary to revise the list of compendia as appropriate for identifying medically accepted indications for drugs.[43]

In recognition of this authority and the changing compendia marketplace, CMS initiated a public process by holding a Medicare Coverage Advisory Committee (MCAC) meeting on March 30, 2006, entitled, "Compendia for Coverage of Off-label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen" to discuss evidence and hear presentations regarding the desired characteristics of published authoritative compendia that may be used by CMS to determine medically accepted indications of drugs and biologicals in an anti-cancer chemotherapeutic regimen.[44] In preparation for the MCAC, CMS reviewed the legal authority governing the addition and removal of compendia and assessed the functionality of the compendia.[45] The agency also acknowledged that "CMS has received requests for official recognition of successor and additional compendia."[46]

Regarding the successor publication, the Deficit Reduction Act (DRA) amended the SSA adding "or its successor publication"[47] after USP-DI in recognition that Thomson™ would change the name of USP-DI by the end of 2007.[48] The Proposed Rule states that CMS is reviewing DrugPoints® to determine if "it is in fact a successor publication rather than a substitute publication."[49] BIO believes that, similar to the USP-DI, DrugPoints® provides timely and accurate clinical information to physicians and should therefore be

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[43] SSA § 1861(t).
[44] 71 Fed. Reg. 4589 (January 27, 2006).
[45] The Agency for Healthcare Research and Quality reviewed the six current compendia and issued a technology assessment available at https://www.cms.hhs.gov/mcd/viewtecassess.asp?where=index&tid=46.
[46] http://www.cms.hhs.gov/mcd/viewmcac.asp?where=index&mid=33.
[47] SSA § 1861(t)(2)(B)(ii)(I).
[48] http://www.micromedex.com/products/drugpoints/
[49] 72 Fed. Reg. at 38,177.

recognized as a successor publication and not a substitute publication. This will give physicians a second option to turn to when deciding the appropriate clinical treatment option for their individual cancer patient.

Additionally, we understand that the National Comprehensive Cancer Network (NCCN) has requested to have its Drugs and Biologics Compendium™ added as an official compendium. BIO appreciates that CMS wants to establish a transparent and predictable process before adding or removing compendia; however, given the fact that there is only one statutorily recognized compendia in the marketplace and the important role that compendia have in affording patient access to innovative cancer care, we urge CMS to also recognize NCCN's Drugs and Biologics Compendium™ by the end of the year and then to focus its efforts on identifying additional compendia that Medicare contractors could use to determine medically accepted indications. The Drugs and Biologics Compendium™ was evaluated by the MCAC and has participated in a process that attempts to achieve many of the goals contained in the process detailed in the Proposed Rule. If CMS believes the Drugs and Biologics Compendium™ has shortcomings, the agency should give NCCN a clear outline of modifications necessary to be listed as well as a timeline for resolution that is much quicker than the next annual process. By immediately recognizing DrugPoints® as a successor publication and adding the Drugs and Biologics Compendium™, CMS will improve Medicare beneficiary access to critical cancer therapies while the agency finalizes this proposed process.

Even though all of the compendia are evidence-based, the content of the compendia may vary due to differences in publication schedules, priorities, review processes, local practices and methods of describing the evidence for each listing. Therefore, to improve the chances of a treatment option being recognized by a compendium in a timely manner, we recommend that CMS continue to recognize multiple compendia for use in Medicare's coverage decisions and allow each compendium the needed flexibility to add new indications. Recognition of additional compendia could protect beneficiary access to advanced cancer therapies by providing physicians and policymakers with a wider body of evidence to use in making treatment and coverage decisions.

BIO also notes that, although CMS' coverage policy for off-label use of drugs and biologicals under Part D is based upon separate statutory authority, it too relies on compendia listings. Thus, while we appreciate that CMS has proposed a process to update the compendia used to determine coverage for oncology therapies Part B, BIO also urges the agency to monitor beneficiary access to medically appropriate uses of drugs and biologicals under Part D, particularly for oral anti-cancer agents not covered under Part B.

B. BIO urges CMS to define compendia to include publications that are indexed by disease.

BIO is concerned with the agency's proposed definition of compendia. CMS states that compendia must be indexed by drug or biological and not by disease-state in order to be recognized for the purposes of determining recognized off-label uses for anticancer treatments.[50] BIO believes that such a requirement is not reflective of the sources oncologists currently use in determining accepted treatments and is an arbitrary requirement in that drug-indexed compendia are not innately more scientifically rigorous than those that are disease-indexed.

In the early 1990s, when Section 1861(t)(2) was added to the SSA, compendia were more uniformly organized by drug. Over the past decade, however, physicians increasingly have begun referencing disease-based compendia to help guide therapeutic choices. This is particularly true in oncology. Today's treatment of many cancers involves multi-drug regimens, and oncologists often turn to compendia that are organized by disease-state to help determine the best and most current regimens for a patient's particular cancer. To allow only drug-indexed compendia to guide coverage policies would mean that oncologists would be expected to cross-reference multiple compendia (those organized by disease-state to those organized by drug) to be certain that *each* drug in a particular regimen will be covered by Medicare. Forcing oncologists to constantly cross-reference therapies is not an efficient use of time or resources. Therefore, BIO urges the agency to remove this requirement and to allow compendia indexed by

[50] Id. at 38,178.

disease as well as by drug or biological to be considered as part of the annual, public review process.

C. BIO urges CMS to minimize approval time.

BIO has specific concerns regarding the proposed timeline for adding or removing compendia, and we urge the agency to provide greater clarification for certain steps in the process. The overall process takes, at a minimum, 225 days. This seems inconsistent with the goals of improving beneficiary access to state of the art care. The process begins with a 45-day notice period that the agency will soon open a 30-day time period to accept completed requests to change the list of compendia.[51] We believe that only a 30 day notice period is necessary because of the streamlined application. Additionally, once CMS finalizes the overall process, compendia will have plenty of "notice" and an understanding of the application process such that they will only need a 30-day notice period prior to CMS accepting requests for compendia changes.

After the conclusion of the 30-day application process, there are two time frames that are not detailed. Specifically, after the 30-day time frame for submitting change requests, CMS has not specified a time period for publishing the list of complete requests or how soon thereafter the agency will initiate the 30-day public comment period regarding the complete requests. We urge CMS to minimize these time periods as any additional time adds to the already lengthy time period for changes to compendia. Similarly, we urge CMS to minimize the time period from issuance of final decision to its effective date. Finally, we urge CMS to re-evaluate the proposed time of 120 days to issue a final decision. We believe that CMS should track the time line it uses for finalizing National Coverage Determinations, requiring CMS to issue a final decision within 90 days of issuing its proposed decision.[52] Taken together our proposal will shorten the time frame while also significantly increasing beneficiary access to cancer treatments.

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[51] Id.
[52] SSA § 1862(l).

Additionally, BIO requests that CMS clarify that approved compendia need not be approved on an annual basis. CMS proposes to issue an annual notice for requests to revise the list of compendia.[53] We ask that CMS clearly state that this notice will not include compendia that are recognized by the Secretary such that the recognized compendia will continue to be recognized until the process removes them. BIO believes that this will establish consistency and stability for the compendia and greater access for Medicare beneficiaries.

D. BIO urges CMS to provide greater detail regarding the grading of evidence process.

The Proposed Rule provides, for the first time, a detailed process for determining changes to recognized compendia.[54] Within this process, CMS proposes a definition for compendia, desirable characteristics of a compendia, and the complete application process.[55] BIO appreciates CMS' approach but urges the agency to provide greater detail and transparency regarding how the agency will "consider a compendium's grading of evidence used in making recommendations regarding off-label uses and the process by which the compendium grades the evidence."[56] BIO believes that this is an essential and critical function of the compendia and central to the prospects of compendia recognition. While we agree that CMS should examine these characteristics of the compendia, the agency needs to clearly detail how it will consider the process the compendia uses for grading evidence and making recommendations. CMS also proposes to consider "any relevant conflicts of interest"[57] in making its determination regarding compendia. BIO urges the agency to define this term and articulate the impact of any conflict of interest.

As CMS improves upon this proposal, BIO urges the agency to maintain a great deal of flexibility in this process as none of the compendia currently appear to satisfy the proposed definition and possess all of the desirable characteristics.

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[53] 72 Fed. Reg. at 38,178.
[54] Id.
[55] Id.
[56] Id. at 38,179.
[57] Id.

We remind the agency that, as stated previously, compendia serve as a vital tool for both physicians and Medicare beneficiaries to access innovative therapies with the goal of increasing and improving timely access to new treatment regimens. Thus, we urge the agency to accept additional compendia promptly.

VIII. TRHCA-SECTION 101(b): PQRI

A. BIO urges CMS to finalize quality measurements that are scientifically valid, consensus-based and that minimize physician burden.

BIO supports CMS' efforts to report and improve the quality of care in the physician office setting, and we look forward to working with the agency on this important issue. BIO encourages CMS to create quality measurements that have been demonstrated to improve quality of patient care, appropriately impact physician decisionmaking, and that impose minimal administrative burdens. As CMS moves forward with implementing quality reporting in the physician office setting, we also urge CMS to be consistent and to update and revise its quality measures to reflect current standards of practice to ensure that Medicare patients receive the most up-to-date and highest quality of care.

CMS states that it interprets section 1848(k)(2)(B)(i) of TRHCA to require that each quality measure be both developed and adopted through a consensus-based process by a consensus organization.[58] CMS further indicates that the statute requires the consensus organizations to consider measures proposed by physicians or specialty organizations.[59] CMS also states that it will require the developing organization to have a comparable level of openness, balance of interest, and consensus based voting participation as the National Quality Forum (NQF) and the AQA Alliance (AQA). BIO supports these foundational principles and encourages CMS to remain consistent with these goals as it finalizes the quality measurements. CMS identifies NQF as a consensus organization; however, the agency concludes that the AQA is not. BIO agrees with this interpretation and we urge CMS to work with the AQA to help it meet requirements necessary of a

[58] 72 Fed. Reg. 38,197.

[59] Id. at 38,197

consensus organization. CMS proposes to incorporate a broad range of quality measurements from the 2007 PQRI, the AMA-Physicians Consortium for Performance Improvement (PCPI), specialty societies such as the American Podiatric Medical Association, and other consensus based measurements. BIO also asks that CMS' final 2008 PQRI quality measures focus on improving quality of care and that they represent a broad range of diseases states that if monitored will improve the quality of care for Medicare beneficiaries.

Finally, BIO urges CMS to be cognizant of the potential burden on physicians that could occur when developing the quality reporting system. BIO is concerned that implementing and complying with CMS' new claims reporting policy may increase administrative burdens for physicians and their staff. CMS should provide clear instruction to physicians and providers to reduce the time and cost associated with implementing new billing requirements and should try to achieve consistency with reporting policies of other payers to further lessen the administrative burden.

B. CMS should take a leadership role with stakeholders to develop consensus recommendations for care coordination quality measures.

In order to further improve the quality of care and foster more efficient use of resources, BIO urges CMS to take a leadership role with stakeholders to develop consensus recommendations for care coordination quality measures. Patients frequently are transferred between care settings, such as between primary care and specialty physicians, different departments in the hospital, or the hospital and the patient's home or a skilled nursing facility. During these transitions, it can be difficult to ensure sufficient communication between providers or across care settings in order provide continuity of care to a patient. Further, patients and their families often bear the burden of initiating follow-up care without sufficient knowledge about their conditions.

In the absence of care coordination, patient safety issues, medication errors, and miscommunication can lead to suboptimal outcomes and increased costs, as

documented by numerous studies.[60] Care coordination is particularly important for vulnerable populations that have chronic health care needs, although everyone that suffers acute illness will need at least temporary care coordination on some level. Because of the relevance of care coordination to all patients and all providers, CMS should encourage consensus organizations to develop appropriate measures at the practice, group, hospital, or organizational level. By expanding the PQRI data set to include measures on care coordination, CMS will improve the quality of care received by patients and will be able to ensure that valuable healthcare resources are used efficiently by avoiding duplication of care.

C. CMS should adopt the three proposed quality measures related to influenza and pneumonia vaccination.

BIO supports CMS' should adopt the proposed quality measures relating to influenza and pneumonia vaccination for the 2008 PQRI. These measures are evidence and consensus-based and are linked to improved healthcare quality outcomes. Adopting these measures will provide health care professionals' incentives to ensure that their patients receive appropriate immunizations —a simple, safe, and cost-effective method of preventing negative health outcomes.

i. Influenza Vaccination Quality Measures

BIO strongly encourages the adoption of the three proposed quality measures related to influenza vaccination for the 2008 PQRI. These quality measures are:

- Influenza vaccination in patients with ESRD;
- Universal influenza vaccine screening and counseling; and
- Influenza vaccination for patients 50 years and older.

Adoption of these measures will lead to higher quality of care due to increased screening, counseling, and influenza vaccination.

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[60] Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century*, Washington, DC: National Academy Press, 2001; EA Coleman et al., *Posthospital Care Transitions: Patterns, Complications, and Risk Identification*, Health Serv Res. 2004 October; 39(5): 1449–1466; AJ Forster at al., *The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital*, Ann Internal Med 2003, 138(3): 161-67.

According to the Centers for Disease Control (CDC), between 15-60 million Americans are infected with influenza every year. Of those, more than 226,000 people are hospitalized from flu complications, and about 36,000 people die. The Medicare population has a higher risk of serious flu complications. More than 90 percent of deaths from influenza-related complications occur in persons 65 years and older. Annual, direct and indirect costs of influenza in the United States have been estimated at more than $12 billion, by the National Coalition for Adult Immunization. CDC's Advisory Committee on Immunization Practices (ACIP) has stated influenza vaccination is the most effective means of preventing influenza virus infection and the potentially serious complications that can arise. ACIP recommends that annual influenza vaccination be given to many groups, including:

- All persons who want to reduce the risk of becoming ill with influenza or of transmitting influenza to others;
- All children aged 6 months through 4 years;
- All adults 50 years and older;
- All adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus);
- Residents of nursing homes and other chronic-care facilities;
- Health-care personnel;
- Healthy household contacts (including children) and caregivers of children <5 years of age and adults ≥50 years of age, with particular emphasis on vaccinating contacts of children less than 6 months of age; and
- Healthy household contacts (including children) and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.

"Healthy People 2010" includes a national health objective of vaccinating at least 90 percent of persons aged 65 and older. However, preliminary data from the National Health Interview Survey estimated that the national influenza vaccine coverage among this population in the second quarter of 2006 to be just 66 percent. Reaching the 2010 goal will require further intervention. The PQRI is an important tool in reaching the 2010 goal because it provides health professionals

with the incentives and information needed to reach the people who are remaining unvaccinated. Protecting Medicare beneficiaries from influenza by ensuring annual vaccination employs an effective measure of quality of care, while reducing health burden and health care costs.

Influenza vaccination for patients 50 years and older already has been endorsed by the NQF and reflects ACIP recommendations in place since 2000. TRHCA requires that quality measures must be adopted or endorsed by a consensus organization, such as the NQF or AQA. Since the standards established by the Act are already met for this measure, adoption by CMS should face no barriers. Hospitalizations, and their associated costs, can be mitigated with a simple, effective and inexpensive influenza vaccine. Analysis of 2006 Medicare fee-for-service data demonstrates that there were more than 30,000 hospitalizations involving influenza in beneficiaries 45 and older, with 89 percent of these involving individuals 65 and older.

Although the other influenza vaccination measures (universal influenza vaccine screening and counseling and influenza vaccination in patients with ESRD) have not yet been adopted by NQF, they are currently under consideration by expert organizations dedicated to health care quality standards. The universal influenza vaccine screening and counseling measure is currently under development by Quality Insights of Pennsylvania and would provide a strong incentive for health care providers to inform their patients of the health care benefits of influenza vaccination. Because these measures will promote greater quality care for Medicare beneficiaries, we encourage their adoption by CMS. Studies have shown physician recommendation is one of the strongest determinants of a patient seeking immunization. Additionally, proper screening helps health professionals identify and advise individuals who might not otherwise have considered immunization.

Adopting the measure for influenza vaccination in patients with ESRD will support improved care for ESRD patients. Although CDC recommends that patients with renal dysfunction be immunized against influenza annually, Medicare billing data reviews show that the ESRD population had a less than 50 percent vaccination rate for the 1997 and 1998 flu seasons. The American Medical

Association's Physician Consortium for Performance Improvement (PCPI) is currently developing this measure. CMS has proposed to select measures under development by the PCPI based upon several factors, including whether the measure will be sufficiently developed and refined for 2008 PQRI implementation, the degree to which they meet the needs of the Medicare program, and their functionality in terms of their ability to be collected and calculated in the PQRI program. PCPI has already published a detailed description of the measure, including information on the numerator, denominator and denominator exclusions, thus showing that the measure is sufficiently developed for use in the 2008 PQRI. Operationally, the provision can be easily implemented and measured, as data collection involved a series of yes/no questions that can be answered through medical records and claims data.

ii. Pneumonia Vaccination Quality Measures

BIO also strongly encourages the adoption of the proposed quality measure related to pneumonia vaccination for patients age 65 years and older. This condition creates a significant disease burden for the elderly population and takes a financial toll on the health care system as a whole; therefore, BIO believes the Medicare program should encourage a more aggressive prevention strategy by including this measure within the PQRI. Pneumococcal bacteremia carries a mortality rate of more than 20 percent in persons aged 65 years and older, even when they are treated with appropriate antimicrobial therapy. The Agency for Healthcare Research and Quality (AHRQ) estimates that the treatment of pneumonia in the 65 and over Medicare population cost approximately $1.8 billion in 2002. Pneumococcal vaccination is recommended for approximately 31 million people aged 65 years and older and for 23 million other people who are considered to be at high risk for infection. According to estimates from the CDC, this risk translates into approximately 40,000 pneumococcal deaths per year in the United States.

Prior vaccination against S. pneumoniae is associated with improved patient survival, a reduction in the incidence of respiratory and renal failure as well as sepsis, and decreased length of stay (an average of 2 days) among hospitalized patients with Community Acquired Pneumonia (CAP). In fact, prior vaccination

reduced both overall mortality and mortality within the first 72 hours following hospitalization. According to the analysis by Fisman et al, increasing the vaccination rates not only saves lives but decreases health care costs by reducing the length of hospital stay required, decreasing the rate of ventilatory support, and reducing the time spent in the intensive care unit. Fisman stated that "on the basis of the conservative assumption that half of the estimated 44,280 adults with invasive pneumococcal disease in 1998 were unvaccinated, an average reduction in length of stay of 2 days for individuals hospitalized with invasive pneumococcal disease would save $36 million annually in Medicare reimbursements alone."

In 1997, ACIP provided recommendations that identified candidates for vaccination, including:

- All persons age 65 years or older;
- Persons 2 to 64 years of age with certain underlying medical conditions; and
- Immunocompromised persons age 2 or older.

Thus, the ACIP recommendations support the proposed PQRI measure for pneumococcal vaccination.

In addition, in 2006 the U.S. Preventive Services Task Force updated its recommendations for preventive services to focus on pneumococcal vaccination. As part of this update process, the Task Force cited 25 recommended preventive services and ranked them based on burden of illness, effectiveness of the service, and use of services and costs of delivery. Two of the top seven services receiving a score of seven or more were immunizations: influenza and pneumococcal. Yet, delivery rates for these services remain low – at around only 50 percent. The proposed PQRI measure would be an important tool for encouraging physician behavior designed to further improve this delivery rate.

In 1997 the national rate of vaccination for persons over age 65 was 45.8 percent. AHRQ recently reported that this percentage had increased to 49.9 percent in 1999 and to 55.7 percent in 2003. However, the Healthy People 2010 goal is 90 percent. In order to achieve this goal, millions more Medicare beneficiaries need to be reached. To date, the main effort to increase vaccination has been the hospital quality measure, applied to those admitted with CAP.

Hospital Compare data indicates that the national rate for the pneumococcal vaccination is 56 percent of those in the hospital with a diagnosis of community-acquired pneumonia – in 2003 that would have been 455,840 patients. Unfortunately, reaching only those hospitalized for CAP is only a small percentage of the overall patients who could and should benefit from this important prevention measure. At this rate, it is estimated it will take 15 years to reach the goal of 90 percent.

In order to save lives and reduce morbidity from invasive pneumococcal infection as well as to realize the associated reduced health care costs, a more aggressive immunization strategy is required. Continued strong public leadership is necessary to address the issue of preventing pneumococcal disease now and not setting it aside to be addressed at a later date. Quality measures for all hospitalized and ambulatory patients over age 65 and for those under 65 who are at risk, based on the ACIP recommendations, are urgently needed. Thus, BIO wholeheartedly supports CMS' leadership in this area and urges the agency to include the pneumococcal vaccination measure in the PQRI for 2008.

IX. Regulatory Impact Analysis

BIO is very concerned about the potential negative impact the projected substantial cut to the conversion factor will have on Medicare beneficiary access to physician care. As noted by CMS, the conversion factor is projected to decrease by 9.9 percent in 2008 under the current statutory formula.[61] According to CMS' impact tables, these cuts are even deeper for hematologists, oncologists, infectious disease physicians, and other physician groups who tend to administer drug and biological therapies when combined with the work and practice expense changes.[62] Although we recognize that CMS has limited statutory authority to address the fundamental flaws with the Sustainable Growth Rate formula, we urge the agency to do anything within its power to mitigate these cuts and to ensure Medicare beneficiaries continue to have access to high quality care.

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[61] 72 Fed. Reg. 38,214.
[62] Id.

X. Conclusion

BIO greatly appreciates the opportunity to comment on the important issues raised by the Proposed Rule, and we look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies. We also applaud CMS' efforts to promote quality care for Medicare beneficiaries and believe that adequate reimbursement is an imperative part of this process. As discussed, it is imperative that Medicare compensate providers adequately for the costs associated with acquiring and administering these therapies in order to ensure that Medicare beneficiaries are not denied access to vital drugs and biologicals administered in physician offices. Please feel free to contact John Siracusa at (202) 312-9281 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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/s/

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