September 24, 2004

BY HAND DELIVERY

Mark McClellan, 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: CMS-1429-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005) – Sections 303, 612, 623, 642, 731(b), and Impact

Dear Administrator McClellan:

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 Medicare physician fee schedule, published in the Federal Register on August 5, 2004 (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 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

---

[1] 69 Fed. Reg. 47488 (Aug. 5, 2004).

1225 EYE STREET, N.W., SUITE 400
WASHINGTON, D.C. 20005-5958

202-962-9200
FAX 202-962-9201
http://www.bio.org

Representing an industry that is devoted to discovering new cures and ensuring patient access to them, BIO continues to be concerned that the major reimbursement changes mandated by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) will have dire consequences for patients. Patients' access to biological therapies is dependent not only on adequate reimbursement for the therapies themselves but also for the unique costs of handling, administering, and preparing them. In just the first six months since CMS began implementing the MMA, we have learned that many providers are worried that they will have to stop treating patients in their offices, forcing their patients to receive care in less convenient, more costly hospital settings.2 Hospitals, in turn, risk becoming overburdened by rapidly growing case loads, potentially causing further delays in patient care. Cuts in reimbursement for drugs and drug administration also would drain providers' ability to offer important yet under-reimbursed support services, such as psychological and nutrition counseling, that enable patients to receive the full benefit of drug and biological therapy regimens.3 Many of the changes implemented to date under Section 303 of the MMA were mandated specifically by the statute. CMS does have some discretion in the way in which it interprets and implements the statutory mandate, however – especially with regard to implementation of the new payment policy in 2005 and beyond. As CMS institutes the MMA's new payment methodologies for drugs and biologicals, it is critical that CMS take care to prevent additional shocks to the Medicare drug delivery system.

BIO is concerned not only about Medicare beneficiaries' ability to receive important biological therapies in 2005, but also about our industry's ability to continue to develop new therapies well into the future. The biotechnology industry is particularly sensitive to changes in Medicare policy. Medicare is the primary payor for most biological therapies, which tend to be injected or infused and treat conditions that primarily affect the disabled and the elderly. Many of these therapies are produced by small companies that have

---

2 During CMS' Pharmaceutical, Pharmacy, and Device Manufacturers Open Door Forum teleconference on Sept. 8, 2004, a provider said that she now is sending patients to hospitals for some therapies and is deeply concerned about her ability to purchase certain drugs at ASP plus 6 percent. See also Rob Stein, Medicare Law Hurts Cancer Patients, Washington Post, Feb. 14, 2004, at A1; Fears Voiced on Bush Medicare Plan, Boston Globe, July 28, 2004, at E2; Ted Griggs, Medicare Change Could Make Cancer Treatment More Costly, Baton Rouge Advocate, Aug. 26, 2004, at ID.

3 See, e.g., Sheri Hall, Reforms May Weaken Cancer Patient Care, Detroit News, Apr. 20, 2004, at A1; Ted Griggs, Medicare Change Could Make Cancer Treatment More Costly, Baton Rouge Advocate, Aug. 26, 2004, at 1D.

few products on the market and are very dependent on continued access to private sector investment. Unless Medicare reimbursement is adequate and predictable, these companies will struggle to fund the development of future innovations.

BIO is committed to working with CMS to ensure that Medicare reform does not disrupt Medicare beneficiaries' access to the best our health care system has to offer. With these critical patient access issues in mind, we address below some specific concerns with the payment policies set forth in the Proposed Rule. First, we renew our request that CMS proactively monitor patient access as payment reforms are implemented and provide simple mechanisms such as a website form and use of the 1-800-Medicare number for patients and providers to quickly and easily report access problems. Second, we urge CMS to implement the MMA's payment reforms in a manner that ensures beneficiary access to vital therapies. In particular, we recommend that CMS immediately provide detailed guidance on the average sales price (ASP) reporting requirements to ensure that manufacturers can supply accurate and complete data for the 2005 payment rates. We urge CMS to seek outside verification of payment rates calculated using ASP information, while also appropriately maintaining the confidentiality of the ASP data it receives from manufacturers. We also request that CMS clarify that new drugs will be paid at wholesale acquisition cost (WAC) or 95 percent of their average wholesale price (AWP) for their first two quarters of marketing, until ASP information can be calculated and uploaded into the payment system.

Third, we ask CMS to reconsider its proposals regarding payment for separately billed renal dialysis drugs, supplying fees, and additional payments for blood clotting factor, because we believe they will fail to protect beneficiary access to important therapies. We support CMS' common sense proposals to reduce the cost and administrative burdens of providing and billing for covered drugs and biologicals, however. Fourth, we ask CMS to provide coverage for new cardiovascular screening tests as soon as they are recommended by the United States Preventative Services Task Force and not to undertake a separate and lengthy national coverage determination review. Fifth, we encourage CMS to adopt the Current Procedural Terminology (CPT) Editorial Panel's recommended revisions to the drug administration codes to better recognize the complexity of administering biologicals. Sixth, we urge CMS to consider methods of covering the items and supplies needed for administration of

intravenous immune globulin (IVIG) in the home. Seventh, we ask CMS to finalize its criteria for coverage of more clinical trials and to further support innovation by more fully implementing the agency's national coverage decision regarding routine patient care costs in other types of clinical trials. Finally, we request that CMS publish ASP-based payment rates for all drugs and biologicals administered in physician offices, even those for which some carriers are applying least costly alternative policies. All of these issues are discussed in greater detail below.

I. Monitoring Patient Access to Drugs, Biologicals, and Physician Services

BIO urges CMS to examine how the changes to Medicare payment for Part B drugs and physician payments affect patient access to drugs, biologicals, and physician services and adopting simple mechanisms for patients and providers to quickly and easily report access issues. CMS stated in January 2004 that it will monitor access to services,[4] and it remains critical that CMS actively and immediately pursue this goal. Access to health care is a serious problem facing Medicare patients now. Earlier this year, during the first wave of MMA implementation, we received reports of providers who were limiting their services or closing their doors to Medicare patients because payment rates were inadequate.[5] These reactions are likely to only get worse in 2005, as the transitional adjustment for drug administration services will be reduced substantially and payments to physicians who administer drug and biological products are projected to decline.[6] If these physicians stop seeing Medicare patients or stop administering critical drug and biological therapies as a result of these sharp decreases in reimbursement, seniors may struggle to find access to the health care they need.

We strongly urge CMS to monitor this problem closely and proactively. We support CMS' plan to "analyze shifts or changes in utilization patterns"[7] and ask the agency to analyze shifts in site of service as well as numbers of

---

4 See, e.g., 69 Fed. Reg. 1083, 1115.

5 Two providers announced during the January 2004 Pharmaceutical Open Door Forum that they would no longer offer infusion services to Medicare beneficiaries because payment rates were inadequate. See also Sheri Hall, Reforms May Weaken Cancer Patient Care, Detroit News, Apr. 20, 2004, at A1; Rob Stein, Medicare Law Hurts Cancer Patients, Washington Post, Feb. 14, 2004, at A1.

6 69 Fed. Reg. at 47566.

7 69 Fed. Reg. at 47573.

procedures performed and total dollars billed. We also encourage CMS to begin monitoring before all of the payment changes go into effect. One immediate way to monitor access would be for CMS to provide an easy mechanism for Medicare beneficiaries and their representatives to submit concerns about access issues directly to CMS. This might include placing a form on the CMS website, in a manner that would be easily accessible to beneficiaries. This would allow patients and providers to offer specific information about access issues and would give CMS a better understanding of the scope of the problem. Another option would be to use the 1-800-Medicare number for providers and patients to report problems they are having regarding access. A combination of these approaches may afford an even greater opportunity to detect problems with access than reliance on a single approach.

BIO recognizes that the MMA mandates certain reports on patient access issues. For example, the MMA directs the Comptroller General to conduct a study on the access of Medicare beneficiaries to physician services under the Medicare program, including an examination of the extent to which physicians are declining to accept new Medicare patients and whether access to physician services has declined over time.[8] The MMA also directs the Medicare Payment Advisory Commission (MedPAC) to study the affect that changes to physician payments have on drug administration services and oncology items and services,[9] including a review of the adequacy of reimbursement in different geographic areas and to different physician practice sizes.[10] The MMA permits the Secretary to make appropriate adjustments to payment for these items and services, beginning in 2007. We appreciate Congress' concern about this issue, and we hope that the Secretary will carefully consider the necessity of any adjustments in 2007. Nonetheless, these reports – and the potential for related adjustments several years from now – are not enough. Medicare beneficiaries need help now. Again, we urge CMS to begin proactively monitoring patient access issues immediately. We would be pleased to work with CMS to develop easy mechanisms – such as a web site form or the 1-800 number – to facilitate the collection of information about these issues today.

---

8 MMA § 604.
9 MMA § 303(a)(5)(A)-(C).
10 MMA § 303(a)(5)(B).

II. Section 303 – Payment Reform for Covered Outpatient Drugs and Biologicals

A. Manufacturers need detailed guidance immediately so they can submit accurate ASP data in October and thereafter

In the new ASP-based reimbursement system, access to drugs and biologicals will depend on the rates calculated using manufacturers' ASP data. It is essential, therefore, that manufacturers obtain the guidance they need to submit accurate data. CMS issued an Interim Final Rule on ASP data submissions in April 2004[11] and another final rule on September 16, 2004.[12] Although we appreciate CMS' recent guidance regarding the use of a smoothing methodology for estimating rebates and chargebacks in order to prevent dramatic swings in ASP, additional issues relating to the estimation methodology still require clarification. Specifically, we ask CMS to clarify whether the final rule's estimation methodology applies to all price concessions or only to those price concessions with respect to which data are lagged. CMS also should provide direction regarding whether and how the final rule's estimation methodology applies to those price concession categories, such as chargebacks, where only some but not all of the price concession data to be incorporated into the ASP calculation are available on a lagged basis.

The agency also has left many other important issues unaddressed. For example, we have asked for clarification as to which drugs and biologicals are subject to the reporting requirements, which entity has the reporting obligation for a particular product, and which sales are exempted from ASP calculations.[13] In addition, we requested that usual and customary prompt pay incentives to wholesalers and distributors not be included in the calculation of ASP.[14] As we approach the final filing deadline before the 2005 rates are calculated, manufacturers still need guidance about these and many other matters so they can file appropriate ASP data, yet CMS says in the September final rule that it will address other issues "at a future time."[15] BIO urges CMS

---

11 69 Fed. Reg. 17935 (April 6, 2004).
12 69 Fed. Reg. 55763 (Sept. 16, 2004).
13 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS, dated June 7, 2004.
14 Id. at 14.
15 69 Fed. Reg. at 55763.

to provide manufacturers with detailed instructions immediately to ensure that next year's payment rates are based on the most complete and accurate data possible.

B. Calculation of ASP-Based Payment Rates

It is critical that CMS accurately calculate ASP-based payment rates for each Healthcare Common Procedure Coding System (HCPCS) code. Errors in setting payment rates may threaten patient access to vital therapies. In the Proposed Rule, CMS explains that it will calculate the ASP for all drug products included in a single HCPCS code by using the volume-weighted average of the manufacturer's ASPs reported to CMS across all the national drug codes (NDC) assigned to the HCPCS code.16 Although this method appears simple, the calculations for HCPCS codes with many manufacturers and package sizes undoubtedly will be complicated. We have seen that mistakes can be made in setting payments even under the less complex AWP-based reimbursement scheme. Many of these errors have been identified and amended because CMS released its background files, which list the NDCs associated with each HCPCS code, helping interested parties verify the agency's calculations and seek corrections.

We believe the ASP calculations will need similar opportunities for public verification and offer a few mechanisms to accomplish this critical function. The first mechanism involves an outside auditor performing the function using the same information available to CMS. Because such information includes confidential sales figures, CMS should not release its full background files to the public. CMS could contract with an outside auditor to verify its calculations, however.

In addition, we ask that CMS promptly compute and release the first quarter 2005 payment rates upon receipt of third quarter 2004 ASP filings. If the agency is able to release the rates in mid-November, manufacturers and other interested parties would have a few weeks before the rates become effective to identify errors, and CMS should have ample time to correct them before they would go into effect. This expedited release should occur each quarter before payment rates are updated. We note also that the public would

16 69 Fed. Reg. at 47521.

be better positioned to identify errors to CMS if the agency were to release a list of the NDCs considered in setting the rate for each HCPCS code, similar to the background files currently available on CMS' website. BIO strongly encourages CMS to ensure this information is readily available.

C. Payment Methodology for New Drugs

Section 1847A(c)(4) of the Social Security Act (SSA), as quoted by CMS in the Proposed Rule,[17] allows the Secretary to pay for new drugs or biologicals at wholesale acquisition cost (WAC)[18] or 95 percent of AWP during the first calendar quarter in which data are not sufficiently available to calculate an ASP. Under CMS' rules, a new product's ASP would not be reported until after its first quarter of sales and would not become effective for use in payment until the start of its third quarter of sales. Therefore, it is not clear how payment rates are to be calculated in the product's second quarter of sales, when the manufacturer's ASP has been reported but is not yet in use. It would appear that the most appropriate policy would be for CMS to continue payment based on WAC or 95 percent of AWP during a new product's second quarter of sales. We believe this is consistent with the congressional intent to have a reference method for setting payment for new drugs until an ASP can be calculated accurately.

D. Payment for Separately Billed Renal Dialysis Drugs (also Section 623)

BIO is greatly disturbed by CMS' proposal to pay for separately billed renal dialysis drugs at ASP minus 3 percent. This payment rate has no basis in law and could threaten beneficiary access to drug and biological therapies, particularly at many smaller facilities. We strongly recommend that CMS reject this proposal in the final rule and instead pay for separately billed dialysis drugs and biologicals at acquisition cost, as the law requires.

The Medicare statute, as amended by section 623 of the MMA, requires CMS pay for separately billed renal dialysis drugs and biologicals at acquisition cost, as determined by a report of the Office of Inspector General (OIG). The

---

17 69 Fed. Reg. at 47251.
18 WAC is not available for all products.

OIG study, completed in May 2004,19 identified average acquisition costs for 10 separately billed drugs used by the 4 largest dialysis providers and 122 other facilities. The OIG found that acquisition costs tended to be higher at the smaller providers,20 and noted that its data do not reflect 2004 price increases, which ranged from 5 percent to 18 percent.21 The OIG's cost data also do not include inventory, working capital, and spoilage/wastage costs estimated to account for 1.5% of total drug costs.22

Rather than basing reimbursement on each drug's acquisition cost, as instructed by the Medicare statute, CMS has proposed to reimburse each drug at ASP minus 3 percent.23 This proposed methodology is deeply flawed for three reasons. First, it conflicts with the clear language of the Medicare statute. Section 1881(b)(13)(A)(ii) of the SSA specifically requires reimbursement to be based on acquisition cost, not ASP. This provision states that the payment amounts for separately billed drugs and biologicals furnished in 2005 are set at "the acquisition cost of the drug or biological, as determined by the Inspector General reports to the Secretary, as required by" MMA section 623(c). The statute's use of "the" acquisition cost of "the drug or biological" compels CMS to use the specific acquisition cost the OIG found for each separately billed drug, rather than a formulaic approach that is tied to ASP. Congress' reference to SSA section 1847A regarding the 2006 payment amounts in section 1881(b)(13)(A)(iii) is also quite revealing in that section 1847A provides for payment rates at ASP plus 6 percent. Aside from the absurdity of establishing payment rates at ASP minus 3 percent in 2005 and at ASP plus 6 percent in the next year, this provision demonstrates that if Congress wanted CMS to set the payment rates for separately billed drugs based on ASP, it knew how to do so. In 2005, it clearly did not, opting instead for payment rates based on acquisition cost.

Second, even if CMS could appropriately state acquisition cost as a percentage of ASP, the proposal's assumed relationship between acquisition cost and ASP is fraught with errors. The OIG requested ASP data from

---

19 OIG, Medicare Reimbursement for Existing End-Stage Renal Disease Drugs, OEI-03-04-00120, May 2004.
20 Id. at 9.
21 Id. at 8.
22 Id. at 9.
23 69 Fed. Reg. at 47522.

manufacturers using the MMA's definition of ASP.[24] As we noted above, however, the MMA's ASP reporting requirements still need many clarifications to ensure that all manufacturers apply them consistently and accurately. Using these potentially erroneous ASPs, the OIG determined that the ASPs for 10 of the top drugs it reviewed averaged 6 percent above acquisition cost at the 4 largest providers and 4 percent below acquisition cost at 122 smaller providers.[25] These conclusions reflect an average relationship between acquisition cost and ASP for all drugs, rather than the relationship for each drug or biological, as required by the Medicare statute. From these conclusions, CMS determined that the average acquisition cost across all 10 top drugs is ASP minus 3 percent. As the OIG explains in its report, the relationship between acquisition cost and ASP varies widely, with ASPs ranging from 19 percent below to 35 percent above acquisition cost.[26] Using the average of ASP minus 3 percent will greatly overestimate the acquisition cost of some products and underestimate the acquisition cost of others, producing inaccurate and potentially inadequate reimbursement rates.

Third, we are concerned about the effects of CMS' proposed methodology on small, independent facilities. The OIG report found that the average acquisition cost for the 10 top drugs at the 122 smaller facilities was above ASP. To pay these facilities at ASP minus 3 percent would require them to lose money each time they administer separately paid drug and biological therapies to Medicare beneficiaries. When these facilities can no longer afford to treat Medicare beneficiaries, patients will be denied the choice of the most appropriate and convenient treatment locations. We urge CMS to protect beneficiary access to care and choice of providers by paying for these 10 separately billed dialysis drugs and biologicals at acquisition cost for independent facilities, updated by the same 3.39 percent annual price growth factor that CMS used in its computation of the drug add-on adjustment to the

---

24 OIG Report at 5.

25 We note that CMS restates the relationship between ASP and acquisition cost (AC) in a confusing manner, which could cause a significant variance in payments to dialysis facilities. Instead of repeating the OIG's findings (ASP = 1.06 x AC), CMS says, "drug acquisition costs were 6 percent lower than ASP." 69 Fed. Reg at 47522. Stated as formulas, the OIG found ASP = 1.06 x AC, or .9434 x ASP = AC. CMS claims AC = .94 x ASP. The difference between these formulas may seem insignificant, but when compared to the $1.8 billion in Medicare reimbursement for separately billable drugs provided by renal dialysis facilities in 2002, it adds up to $6.12 million. We point out this difference to emphasize the importance of clearly and carefully explaining how CMS reaches its payment rates.

26 OIG Report at 10.

composite rate.27 Payment at acquisition cost is required by the statute, and using the acquisition cost for independent facilities, updated to reflect inflation since the OIG collected its data, will best ensure patients access to the treatments they need. For drugs and biologicals that were not included in the OIG report, BIO recommends payment at ASP plus 6 percent.

E. Reporting and Billing for Physicians' Services Associated with Administration of Covered Outpatient Drugs

The MMA created an important window of opportunity for CMS to establish more appropriate coding and reimbursement for drug administration services. The MMA exempts certain changes in expenditures due to CMS' evaluation of the existing drug administration codes from the budget neutrality requirement that would otherwise apply.28 BIO believes this review is fundamental to CMS' efforts to reimburse more appropriately for drugs and biologicals and their administration services. Only when these products and services are accurately recognized by the coding system can CMS begin to truly improve its reimbursement methodologies. At BIO, we strongly believe that reimbursement and coding need to distinguish between uncomplicated administrations of simple products, such as saline, and complex administrations of advanced biologicals. Biological products are not only more costly than saline, but they require administration by specially-trained nurses, precise reconstitution, and careful monitoring to control the risk to the patient and to achieve their full effectiveness. These additional requirements must be reflected in coding and reimbursement for the administration services.

The American Medical Association (AMA) CPT Editorial Panel recently approved 12 new and 14 revised codes that will better reflect the varying levels of complexity and resource consumption associated with each drug administration service.29 BIO applauds CMS' plan to use G-codes as placeholders for new CPT codes,30 and we urge CMS to adopt the CPT Editorial Panel's proposals to improve the recognition of the administration of complex drug and biological therapies in the coding system no later than January 1, 2005.

---

27 69 Fed. Reg. at 47528.
28 SSA § 1848(c)(2)(B)(iv).
29 AMA, CPT Editorial Panel, August 2004 Meeting, Changes to Drug Administration Codes, available at http://www.ama-assn.org/ama1/pub/upload/mm/362/panelactionsdruginf2.doc.
30 69 Fed. Reg. at 47522.

F. Payment for Items and Services Associated with Furnishing Blood Clotting Factor

CMS proposes to make a $0.05 per unit separate payment to hemophilia treatment centers and homecare companies for the items and services associated with furnishing blood clotting factor.[31] We are deeply concerned that this amount is not sufficient to protect beneficiary access to these critical therapies, especially in light of payment cuts for clotting factor products. CMS proposed the same additional payment last year, and as noted in the Proposed Rule, many commenters responded that the payment was too low and would "severely impact beneficiaries' access to clotting factor."[32] After reviewing a January 2003 General Accounting Office (GAO) report, as instructed by the MMA, CMS proposes the same $0.05 rate. The passage of time has not made this rate adequate to cover the costs associated with mixing, storing, and delivering clotting factors, supplies, and patient training. We urge CMS to examine more recent data than the 2000-2001 data in the GAO study and propose a new rate that will appropriately reimburse providers and ensure patient access to life-saving clotting factor.

G. Supplying Fees

MMA section 303(e)(2) requires CMS to pay a supplying fee for immunosuppressive drugs, oral anti-emetic drugs used as part of an anticancer chemotherapeutic regimen, and oral anticancer chemotherapeutic drugs and biologicals. CMS proposes to set this fee at $10 per prescription. BIO shares CMS' goal of "assur[ing] that each beneficiary who needs covered oral drugs has access to those medications,"[33] yet we doubt that this supplying fee is sufficient to "cover a pharmacy's activities to get oral drugs to beneficiaries."[34] CMS reached the $10 rate after reviewing comments from pharmacies supporting supplying fees ranging from $12 to $56 per prescription. CMS rejected the recommendations for fees over $44, but did not fully explain how it determined that the rate should equal the lowest identified cost of dispensing any prescription to a Medicare beneficiary. Although we appreciate CMS' efforts to cut pharmacies' costs through reforms to the billing requirements,

---

31 Id.
32 69 Fed. Reg. at 47523.
33 Id.
34 Id.

discussed below, we are not convinced that $10 per prescription is adequate to cover the costs of providing immunosuppressive and oral anticancer drugs. We urge CMS to work with pharmacies to analyze the costs of providing these important therapies in order to protect beneficiary access to them.

H. Reforms to Billing Requirements and Shipping Time Frames

BIO applauds CMS' common sense reforms to the billing requirements and shipping time frames for supplying covered immunosuppressive and oral drugs to Medicare beneficiaries.35 These reforms will eliminate some of the paperwork and delays associated with obtaining payment for these therapies and will help reduce pharmacies' administrative expenses. The shipping time frame revision, allowing shipment of refills earlier in the month, should reduce patients' concerns about late-arriving medications and save the expense of using overnight shipping. We ask CMS to implement these reforms in the final rule.

III. Section 612 – Cardiovascular Screening Blood Tests

Effective January 1, 2005, section 612 of the MMA provides Medicare coverage for cardiovascular screening blood tests for early detection of cardiovascular disease or abnormalities associated with an elevated risk of cardiovascular disease. Not only are cholesterol and other lipid triglyceride tests covered, but the Secretary also may extend coverage to other screening tests for indications associated with cardiovascular disease, including indications measured by non-invasive testing if the United States Preventative Services Task Force (USPSTF) recommends them.36 In the Proposed Rule, CMS proposes coverage of three screening blood tests for conditions associated with cardiovascular disease. The agency then proposes that the extension of the benefit to other tests only would be made if the agency determines they are appropriate through the National Coverage Determination (NCD) process.37

BIO is concerned that the NCD process will be too slow and cumbersome38 to keep up with the current practice of medicine. Moreover, the

---

35 Id. at 47523-24.
36 Id. at 47516.
37 Id. at 47517.
38 The NCD process is lengthy because it involves the agency's review and evaluation of the clinical and scientific issues surrounding coverage. Even with changes to the NCD process by the MMA, an NCD

NCD process is unnecessary because the MMA requires that any new screening test must be recommended by USPSTF in order to be covered. The USPSTF is "an independent panel of experts in primary care and prevention that systematically reviews the evidence and effectiveness and develops recommendations for clinical preventive services," working with outside experts, liaisons from major primary care societies, public health service agencies, and evidence-based practice centers.39 The 15 members of the panel work with other experts and the Agency for Healthcare Research and Quality's Evidence-based Practice Centers to develop guidelines for preventive care. They include experts from a range of specialties, including internal medicine, geriatrics, preventive medicine, and public health.40

BIO firmly believes that the lengthy NCD process is unnecessary given the USPSTF's role and its extensive expertise and high quality review process.41 In addition, use of the NCD process is not required by the statute.42 Instead, CMS should save its valuable resources by providing immediate coverage for services recommended by the USPSTF. This way, patients would have access to cutting-edge screening tools as soon as they are recommended by USPSTF, and CMS' additional review will not create further delays. BIO urges CMS to forgo the NCD process and instead adopt the USPSTF's recommendations on screening tests for conditions associated with cardiovascular disease as soon as they are adopted, speeding Medicare beneficiaries' access to such lifesaving tools.

IV. Section 642 – Extension of Coverage of IVIG for the Treatment of Primary Immune Deficiency Diseases in the Home

---

determination can take up to six months if a request does not require an external technology assessment or Medicare Coverage Advisory Committee review, and up to nine months if either types of reviews are required. See MMA § 731.

39 "About USPSTF," U.S. Preventive Services Task Force, AHRQ Publication No. 00-P046, January 2003, Agency for Healthcare Research and Quality, Rockville, MD, available at http://www.ahrq.gov/clinic/uspstfab.htm.

40 Id.

41 Although we do not question the expertise of the USPSTF, we would appreciate more information about the process that USPSTF undertakes in its considerations. We urge the task force to meet frequently enough and make expeditious recommendations such that Medicare beneficiaries are not denied access to new cardiovascular screening tests.

42 The MMA does not require that the Secretary use the NCD process to approve new cardiovascular screening tests.

CMS proposes to implement section 642 of the MMA, expanding Medicare coverage for IVIG administered in the home.43 We appreciate CMS' efforts to implement this provision in a timely manner, but we remain concerned that the items and services related to administration of IVIG in the home are not covered. BIO urges CMS to extend coverage for the important items and services necessary to administer IVIG through its proposed rule on Part D. We will submit comments to the agency's proposed rule implementing the new Medicare Prescription Drug Benefit44 in this regard and ask the agency to give them thoughtful consideration. Ultimately, we support CMS' view that Part D should wrap around Part B coverage, filling "any gaps in existing Part B coverage" – such as the need for beneficiaries to have access to the items and services necessary to administer IVIG in their homes.45

V. Section 731(b) – Coverage for Routine Costs of Category A Clinical Trials

BIO appreciates CMS efforts to expand coverage for the routine costs of Category A clinical trials.46 This proposal, required by section 731(b) of the MMA, will encourage beneficiary participation in more clinical trials, which is essential for providing new hope for patients and advancing our understanding of how to treat illness. We ask CMS to further support innovation by more fully implementing its national coverage decision regarding routine patient care costs in other types of clinical trials. CMS first announced its coverage of the routine costs associated with clinical trials in 2000, yet the full potential of this policy has not been achieved because CMS has not issued the criteria for trials not automatically deemed to be qualified clinical trials. BIO urges CMS to issue the long overdue self-certifying criteria so that more trials can qualify for reimbursement of routine patient care cost thus facilitating greater participation by Medicare beneficiaries in clinical trials.

VI. Impact – Publishing ASP-Based Payment Rates for All Drugs and Biologicals

---

43 69 Fed. Reg. at 47525.
44 69 Fed. Reg. 46632 (Aug. 3, 2004).
45 See 69 Fed. Reg. at 46648.
46 69 Fed. Reg. at 47543.

Finally, BIO requests that CMS publish ASP-based payment rates for all drugs and biologicals administered in physician offices, even those for which some carriers are applying least costly alternative (LCA) policies. Specifically, an ASP-based rate should be published for J9217 (Leuprolide acetate suspension) as well as for J9202 (Goserelin acetate implant). CMS published just one rate, $234.28, for these two codes because it "assumed that Medicare carriers are applying 'least costly alternative' pricing and are using the J9202 price for J9217."47 The OIG has identified 10 jurisdictions that do not use LCA pricing or do not apply it to J9217.48 In addition, many other states have "grandfathering" clauses for patients who were using Leuprolide acetate suspension prior to implementation of LCA or make exceptions for patients for whom the therapy is medically necessary.49 Even more troubling, CMS appears to be inappropriately mandating a national policy of LCA through its action. LCA's are local policies that can be adopted by a carrier only if it follows specific procedural safeguards set out in the Program Integrity Manual and makes specific findings supported by clinical evidence. CMS should not suggest that it endorses any particular carrier's LCA policy.

CMS acknowledged during the September 8, 2004, Pharmaceuticals, Pharmacy, and Device Open Door Forum that it erred by not publishing an ASP-based rate for J9217. BIO thanks CMS for announcing the correct rate for J9217 during the Open Door Forum, and we urge CMS to publish ASP-based payment rates for all drugs and biologicals administered in physician offices – including those for which some carriers are applying LCA policies – to ensure beneficiary access to them. CMS also should clearly state in the final rule that

---

47 Id. at 47563, 48567.

48 "OIG Draft Report: Medicare Reimbursement for Lupron," OEI-03-03-00250, January 2004, p. i (stating "We found that carriers in 10 of 57 jurisdictions did not apply a least costly alternative policy to Lupron."); see, e.g., Blue Cross and Blue Shield of Montana, "LMRP for Leuprolide Acetate (Lupron)"/ "Leuprolide – Lupron;" see, also, Wisconsin Physicians Services Insurance Corporation policies for Michigan, Illinois, and Wisconsin.

49 See, e.g., Blue Cross and Blue Shield of Arkansas, "LCD for Leuprolide Acetate/Goserelin," L12127; Empire Medicare Services, "LMRP for Luteinizing Hormone-Releasing Hormone (LHRH) Analogs for Treatment of Malignant Neoplasm of the Prostate," (L3751); see, also, Memorandum from Thomas A. Scully, Administrator, CMS, to Dara Corrigan, Acting Principle Deputy Inspector General, OIG, regarding "OIG Draft Report: Medicare Reimbursement for Lupron," p. 1 (stating "all LCA policies affecting payment for Lupron specify that full payment will be made if the physician states that the use of Lupron rather than the LCA drug is medically necessary."); see, e.g., National Heritage Insurance Company (NE), "LCD for Gonadotropin-Releasing Hormone Analogs- Leuprolide Acetate (Lupron, Eligard, Viadur), Goserelin Acetate (Zoladex)**;"** Blue Cross and Blue Shield of Arkansas, "LCD for Leuprolide Acetate/Goserelin," L12127; Blue Cross and Blue Shield of Kansas, "LMRP for Lupron/Zoladex" (L9281).

it does not mandate a national LCA policy for any drug, including Leuprolide acetate suspension.

VII. Conclusion

In sum, BIO is concerned that the major reimbursement changes created by section 303 of the MMA will have serious ramifications for patients and urges CMS to make patient access the agency's primary focus as it implements this section. With this goal in mind, BIO urges CMS to:

- proactively monitor patient access issues as payment reforms are implemented and provide simple mechanisms such as a website form and use of the 1-800-Medicare number for patients and providers to quickly and easily report access issues;

- provide manufacturers with detailed guidance immediately so they can submit accurate ASP data before the third quarter deadline;

- seek outside verification of its ASP calculations, publish rates as soon as feasible to give the public the opportunity to identify errors, and publish a list of NDCs included in each HCPCS code's ASP;

- clarify that payment for new drugs should be based on WAC or 95 percent of AWP until a payment rate for such products can be determined based on manufacturer reported ASP information;

- pay for the 10 top separately billed renal dialysis drugs and biologicals at the acquisition cost determined by the OIG, as the Medicare statute requires, preferably using the acquisition cost found for independent facilities, updated for inflation;

- pay for separately billed renal dialysis drugs and biologicals not included in the OIG report at ASP plus 6 percent;

- adopt the CPT Editorial Panel's revisions to coding for drug and biological administration services as G-codes effective in 2005;

- increase its proposed additional payment for blood clotting factor to ensure beneficiary access to these therapies;

- work with pharmacies to determine an appropriate level for supplying fees for oral anticancer, anti-emetic, and immunosuppressive drugs;

- implement its common sense reforms to its billing requirements and shipping time frames for covered drugs;

- provide coverage for new cardiovascular screening tests as soon as they are recommended by the USPSTF;

- explore methods of covering under Part D the items and supplies needed for administration of IVIG in the home;

- issue self-certifying criteria relating to clinical trials so that more beneficiaries can participate in such trials; and

- publish ASPs for all drugs and biologicals administered in physician offices, even those for which some carriers are applying LCA policies.

BIO appreciates the opportunity to comment on the important issues raised in 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 sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact Michael Werner at (202) 962-9200 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Carl B. Feldbaum
President