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October 10, 2006

VIA HAND DELIVERY

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: File Code CMS-1506-P; Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Calendar Year 2007 Rates; Proposed Rule

Dear Dr. McClellan:

Novo Nordisk Inc. (Novo Nordisk) appreciates the opportunity to submit these comments regarding the Outpatient Prospective Payment System (OPPS) Proposed Rule for Calendar Year (CY) 2007. Novo Nordisk is a focused healthcare company and world leader in diabetes care and other pharmaceutical products. The company has the broadest diabetes product portfolio in the industry and also has a leading position within areas such as hemostasis management. We develop, manufacture, and market pharmaceutical products that make a significant difference to our society – patients, the medical profession, and importantly, to Medicare beneficiaries.

Below we present our comments to (1) encourage the Centers for Medicare and Medicaid Services (CMS) not to decrease payment for clotting factor in the hospital outpatient setting, (2) seek to clarify that the proposed outpatient hospital rule is not intended to have an effect on inpatient reimbursement for clotting factor (which has been the focus of a separate rule-making process), (3) applaud CMS for continuing to pay the hemophilia clotting factor furnishing fee, and (4) discourage CMS from decreasing payment for non pass through specified covered outpatient drugs to 105% of ASP.

I. Hemophilia Clotting Factor Payment

As the manufacturer of NovoSeven® [Coagulation Factor VIIa (Recombinant)], a biopharmaceutical indicated for the treatment of hemophilia A or B in patients with inhibitors to Factors VIII and IX, we are concerned by the proposed decrease in clotting factor payment from the current Average Sales Price plus six percent (ASP+6%) to Average Sales Price plus five percent (ASP+5%) in the hospital outpatient setting.

A. CMS Should Not Decrease Payment for Clotting Factor in the Hospital Outpatient Setting.

Many of our nation's hemophilia treatment centers (HTCs) – the primary providers of care for patients affected by this debilitating disease - are reimbursed by Medicare under the hospital outpatient methodology. We fear that the negative financial impact of the proposed payment decrease will not only compromise the quality of care they can deliver, but the quality of life for their Medicare patients. Novo Nordisk is concerned that the proposed reduction in payment will erode the ability of hospital outpatient departments to supply clotting factors to patients, particularly given the unique expenses associated with storage and handling of clotting factors.

Novo Nordisk recognizes that CMS made a significant effort in 2005/2006 to make Medicare payment for hemophilia products consistent across all settings of care (inpatient, outpatient, physician office/HTC, and home health). Novo Nordisk supported this CMS effort and believes the standardized payment across settings of care ensures patient access to clotting factors whenever and wherever it is needed. To maintain uniformity of payment across all settings of care - the physician office, HTC, the inpatient setting, as well as the outpatient setting of care - Novo Nordisk encourages CMS to continue to pay for clotting factor in the hospital outpatient setting at ASP+6%.

B. Should CMS Decrease Payment for Clotting Factor in the Hospital Outpatient Setting, the Hospital Inpatient Setting Must Not be Affected.

Under the OPPS, CMS proposes to pay for blood clotting factors based on ASP+5% and to pay for the furnishing fee using an amount updated for CY 2007 (discussed below).[1] During rulemaking for Fiscal Year (FY) 2006 and 2007, CMS articulated the desire to pay for clotting factors consistently across all settings of care.[2] It is unclear what, if any, effect that CMS intends for the OPPS proposal to have on the reimbursement for inpatient use of clotting factors. However, based on the OPPS Proposed Rule's lack of clarity, and CMS' stated intent to pay for clotting factors consistently across all settings of care, we have some concern that CMS may attempt to apply the ASP+5% payment rate to the inpatient setting for FY 2007. To the extent that CMS is proposing to alter inpatient rates through the Proposed Rule, its proposal is inconsistent with the underlying statutory mandate and has been offered in a manner that does not provide adequate notice or an opportunity for comment as required by the Administrative Procedure Act. We strongly oppose any such proposal and have outlined our argument against such an action below.

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[1] 71 Fed. Reg. 49506, 49,586 (Aug. 23, 2006).

[2] FY 2006 Hospital Inpatient Prospective Payment System, Proposed Rule. 70 Fed. Reg. 23453-4, 23482 (May 4, 2005); FY 2006 Hospital Inpatient Prospective Payment System, Final Rule. 70 Fed. Reg. 47473, 47506 (Aug. 12, 2005); FY 2007 Hospital Inpatient Prospective Payment System, Final Rule. 71 Fed. Reg. 48125, 48165 (Aug. 18, 2006).

Taking this action would violate the payment provisions on administration of blood clotting factors to inpatients in CMS' duly-promulgated final rulemaking, "Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates" Final Rule (IPPS Final Rule).[3] We note that we present these arguments due to lack of clarity and hope that CMS does not, in fact, intend for the outpatient rule to affect the inpatient setting for FY 2007 or subsequent years.

In August, CMS finalized the payment provisions for administration of blood clotting factor in the inpatient setting in the IPPS Final Rule. In the preamble to the FY 2007 IPPS Final Rule, CMS explained that it amended its regulations at 42 C.F.R. §§ 412.2(f)(8) and 412.115(b) in the FY 2006 IPPS Final Rule to provide that, for discharges occurring on or after October 1, 2005, blood clotting factor payments in the inpatient setting are made based on the Medicare Part B payment amounts for blood clotting factors as "determined under Subpart K of 42 CFR Part 414 . . . ."[4]

Subpart K of 42 C.F.R. Part 414 specifically provides in Subsection 414.904 that payments for drugs or biologicals under Medicare Part B are based on the "lesser of the actual charge on the claim for program benefits or 106 percent of the average sales price," subject to certain limitations.[5]

CMS did not implement any changes to the payment for blood clotting factors under these regulations in the FY 2007 IPPS Final Rule. Rather, in the text itself, CMS confirmed its continued intent to pay for blood clotting factors administered to inpatients at ASP+6%:

> In section VIII of the preamble to this final rule, we are providing that fiscal intermediaries continue to make payment amounts for blood clotting factor administered to hemophilia inpatients using the Medicare Part B payment amounts determined under Subpart K of 42 CFR Part 414 . . . . By using the Medicare Part B Drug Pricing File, Medicare will be making consistent payments for blood clotting factor provided to inpatients and outpatients. For further updates on pricing, we refer reader[s] to the Medicare Part B drug pricing regulations.[6]

CMS is bound to follow this finalized rulemaking, which was promulgated following a notice-and-comment period, and implement the 106 percent payment rate for FY 2007 as called for by the FY 2007 IPPS Final Rule.[7] The OPPS Proposed Rule is specifically limited to OPPS issues and does not, on its face, address the separately considered

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[3] 71 Fed. Reg. 47,870, 48,125, 48,165 (Aug. 18, 2006).
[4] 71 Fed. Reg. at 48,125.
[5] 42 C.F.R. § 414.904(a) (1)-(2).
[6] 71 Fed. Reg. at 48,165.

[7] *See Service v. Dulles*, 354 U.S. 363 (1957) (asserting that after an agency issues a duly-promulgated regulation, the agency is bound by that regulation unless it is inconsistent with a statute or a subsequent, more authoritative regulatory provision).

issue of IPPS payment. It cannot be a vehicle for changing the policy duly reflected in the IPPS Final Rule.

CMS released the IPPS Final Rule on August 1, 2006 and the OPPS Proposed Rule on August 8, 2006. Based on the short interval between the release of these two rules, CMS must have foreseen at the time it issued the IPPS Final Rule that it would be proposing changes to the payments for blood clotting factors in the OPPS Proposed Rule that, if applied in the inpatient setting, would have significant consequences for payments in the inpatient setting.

To the extent that CMS does intend the OPPS Proposed Rule to alter IPPS payment, CMS' failure to clearly state its intent means that interested parties have not received adequate notice of the proposed revision. Proposing changes in the OPPS Proposed Rule that will substantially alter a final rulemaking without providing interested parties an opportunity for notice and comment violates the principle of fundamental fairness upon which the administrative rulemaking system is based. For this and the other reasons stated above, Novo Nordisk believes CMS should not move forward with any changes to the FY 2007 IPPS payment rates for clotting factors, to the extent that it was considering doing so.

C. CMS Should Continue to Pay the Hemophilia Clotting Factor Furnishing Fee.

Novo Nordisk supports CMS' plan to continue paying the furnishing fee for clotting factors for hemophilia, set annually in the Medicare Physician Fee Schedule (MPFS). This furnishing fee, currently set at $0.146 per unit of clotting factor, helps to offset the cost of special storage and handling requirements (e.g.: refrigeration at 36-46° F and the need to avoid exposure to direct sunlight) in order to provide these products to Medicare beneficiaries).

As the furnishing fee for 2007 will not be finalized until the release of the CY 2007 MPFS final rule, we must however, express our concern that it will not be sufficient to cover these significant costs, particularly if CMS were to implement the proposed 1% of ASP decrease in clotting factor payment.

II. CMS Should Not Decrease Payment for Non Pass Through Specified Covered Outpatient Drugs.

Novo Nordisk is concerned about the overall reduction in payment for specified covered outpatient drugs (SCODs) in OPPS. Hospitals should receive adequate payment for all aspects of providing drugs and biologicals in this setting of care. Currently, CMS reimburses separately paid drugs and biological products administered in hospital outpatient departments at ASP+6% for both pass through products and SCODs. For 2007, CMS proposes to reduce drug payment for SCODs to ASP+5%.

Novo Nordisk believes that payment at ASP+5% may not be sufficient to ensure beneficiary access to appropriate therapies. Despite CMS' findings outlined in the proposed rule that ASP+5% would be adequate payment, we ask that CMS seriously consider other analyses submitted by stakeholders during the comment period which may demonstrate the contrary. Novo Nordisk recommends that CMS maintain hospital outpatient drug payment for non pass through SCODs, at a minimum, at ASP+6%.

More specifically, we believe that the proposal to pay for all SCODs at 105 percent of ASP is inappropriate for the following three reasons: (1) it is inconsistent with a plain reading of the Social Security Act (the Act), (2) CMS' analysis supporting the proposal fails to differentiate between costs and charges, and (3) the proposed reduction will, we fear, have a negative effect on access.

A. The Proposal is Inconsistent with a Plain Reading of the Social Security Act.

In CY 2006 and subsequent years, Section 1833(t) (14) (A) (iii) of the Act requires that payment for SCODs be equal to the average acquisition cost of the drug for that year. Although CMS has suggested that, on average, hospitals could acquire a range of drugs at 105 percent of ASP for CY 2007, we question both the legal basis and analytical strength of this proposal.

In particular, Novo Nordisk deeply concerned about the Agency's application of Section 1833(t) (14) (A) (iii) because we believe this application is inconsistent with a plain reading of the statute. The Act does not contemplate the calculation of ambulatory payment classification (APC) payment rates on a composite basis. Section 1833(t) (14) refers to the payment for "a specified covered outpatient drug" covered as part of a hospital outpatient department service.[8] The statute goes on to define the amount of payment as "the average acquisition cost for the drug."[9] The plain language of the Act dictates that drug APC payment rates must be determined on an individualized basis, with references to "a . . . drug" and "the drug" in the singular form.

It is a well-established rule of law that the plain language of a statute must be honored by a regulatory agency.[10] Regulatory agencies do not have the discretion to deviate from the plain language of a statute.

Even if CMS' conclusion was correct that, on average, hospitals may acquire all 500 drugs and biologicals at 105 percent of ASP (which we question below), that fact is irrelevant in determining the drug APC payment rates prescribed by the Act. Congress could have required CMS to take into account the average price at which hospitals

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[8] Emphasis added.

[9] *Id.*

[10] *See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984) (requiring that the court determine whether Congress' intent regarding the issue in question is clear, and if not, whether the agency's interpretation "is based on a permissible construction of the statute"); *see also United States v. Mead Corp.*, 533 U.S. 218 (2001).

acquire all drugs. It did not, and we can find no evidence that Congress intended that CMS determine drug APC payments rates on anything other than a drug-by-drug basis.

B. The Reasoning Supporting the Proposal is Unsound.

In addition to our legal concerns, we believe that the proposal fails to differentiate between costs and charges. The proposal appears to be based on the premise that charges are adequate to cover acquisition and related costs. We question the accuracy of this assumption and challenge the validity of the Medicare Payment Advisory Commission (MedPAC) information cited to corroborate this assertion.[11] On their face, MedPAC's conclusions appear to be unsound and unsupported.

We are troubled by the fact that MedPAC's conclusions are not based on statistically significant survey results that reflect charging practices, but instead on informal consultations which may or may not accurately reflect practices in the marketplace. Novo Nordisk believes the proposal is arbitrary and capricious when applied to individual drugs because, given our concerns about the nature of the data used and the methodology employed, the proposal provides no assurance that the payment covers the acquisition cost for the drug and related costs.

Additionally, we disagree with the Agency's reasoning behind the proposal, which appears to conclude that a payment rate determined by reducing charges to costs would be appropriate to cover handling and acquisition costs simply because hospitals set charges for drugs high enough to reflect handling costs and acquisition costs. At best, we believe CMS' analysis suggests that payment at charges may be adequate.

Novo Nordisk also has significant concerns about CMS' proposed methodology for determining the average reimbursement from charges reduced to costs. For example, in stating that 105 percent of ASP for the fourth quarter 2005 was equal to the mean costs derived from the CY 2005 hospital claims data, the Proposed Rule did not specify whether CMS considered all CY 2005 claims data or just the data for the fourth quarter of that year. Given the well-established concerns that have been articulated with CMS' OPPS methodology generally and the accuracy of the cost data used, we do not believe that the OPPS claims data provides any meaningful support for the Agency's methodology. Significantly, Congress has directed the Agency to use data beyond the OPPS claims data in determining SCOD costs, and the data used by MedPAC is insufficient and merely anecdotal.

C. The Proposal Reflects a Poor Policy Decision that Will Likely Have an Adverse Effect on Access.

In addition to the legal and analytical issues presented, we believe that the proposed reduction reflects a poor policy. This proposal can only be implemented at the expense of beneficiaries treated with drugs that hospitals cannot acquire consistent with the

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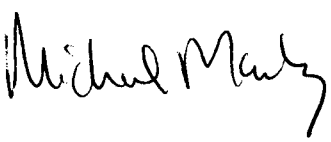
[11] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, Ch 6, "Payment for Pharmacy Handling Costs in Hospital Outpatient Departments," 141 (Jun. 2005).

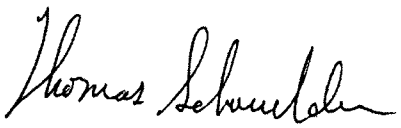
proposed reimbursement. Using an average, composite approach necessarily means that some hospitals will be forced to lose money each time some drugs are administered. This will almost certainly discourage hospitals from continuing to administer some products, thus eroding beneficiary access to important therapies. In revising drug payment rates under the Medicare Modernization Act, we believe that Congress intended to account for the acquisition price of drugs more accurately. Novo Nordisk does not believe that Congress had any intention of impinging on beneficiary access to drugs. As such, we urge you to reconsider this unfounded proposal which has the potential to negatively impact beneficiary access.

III. Conclusion

Thank you for the opportunity to submit these comments on the OPPS CY 2007 Proposed Rule. Should you have any questions, please contact Mike Mawby at (202) 626-4521 or Thom Schoenwaelder at 609-9190-7886. .

Sincerely,





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Re: CMS-1506-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates)

Dear Administrator McClellan:

On behalf of the Oncology Nursing Society (ONS) - the largest professional oncology group in the United States, composed of more than 33,000 nurses and other health professionals dedicated to ensuring and advancing access to quality care for all individuals affected by cancer - we appreciate this opportunity to submit comments regarding the proposed 2007 Hospital Outpatient Prospective Payment System (HOPPS). As part of its mission, the Society stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that will reduce and prevent suffering from cancer, particularly among the Medicare population which is disproportionately affected by cancer.

Hospital Outpatient Departments Require Additional Resources

As you know, hospital outpatient departments play a critical role in the delivery of cancer care. ONS members work in hospital-based settings - both inpatient and outpatient - as well as in physician offices. We are concerned that oncology nurses in all care settings are reporting that the resources available to them are diminishing and, in some cases, insufficient Medicare payment is posing a serious threat to access to quality care for certain beneficiaries. Of particular concern is that our members have reported in surveys in 2004 and 2005 that referrals from physician offices to hospital outpatient departments are on the rise; at the same time our members and the Association of Community Cancer Centers indicate that payment rates for cancer care in outpatient departments are on the decline. This intersection of two significant challenges - additional demand and diminished resources - poses a serious threat to access to care in hospital outpatient departments.

In both the 2004 and 2005 survey, our members reported that a majority of the patients who are being referred from physician office settings to hospital outpatient departments are Medicare patients without supplemental coverage. This change in referral practices has serious

implications, as it likely is placing significant burden on an already strained hospital outpatient cancer care system that may not be able to support or accommodate additional patients. Particularly, if a majority of these "new" hospital outpatient department cancer patients are Medicare beneficiaries who do not have supplemental insurance, they may not have the resources to meet their out-of-pocket or coinsurance requirements - further contributing to the financial strain experienced by community cancer centers.

ONS Recommendations

ONS feels strongly that the nation will be able to sustain and bolster the safety-net of community-based cancer care and continue to deliver quality, comprehensive cancer care to all in need, ***only*** if Medicare provides increased reimbursement for chemotherapy drugs and their administration - in all cancer care settings. The Society maintains that people with cancer should be assured access to comprehensive quality care that proves the most effective and appropriate for them and such care should be accessible in whichever care setting is preferred.

As such, ONS advocates that CMS boost payments for the full range of care and services provided to Medicare beneficiaries with cancer who are treated in hospital outpatient departments. We urge you to provide increased and additional payments for the full range of oncology nursing services provided in hospital outpatient departments, particularly the care related to chemotherapy and supportive drug administration, as well as evaluation and management. Further, we encourage your full and fair consideration of the specific comments submitted by the Association of Community Cancer Centers, particularly the recommendations for drug administration and evaluation and management services.

Summary

Please know that we stand ready to work with you, your colleagues, and other cancer community stakeholders to craft and implement Medicare payment policy changes that ensure access to quality cancer care for seniors with cancer and prove fiscally responsible for the nation. We thank you for this opportunity to submit comments and are grateful to you and your colleagues for your consideration of our views. As always, if we can be of any assistance to you, or if you have any questions, please feel free to contact us or our Washington, DC Health Policy Associate, Ilisa Halpern Paul (202/230-5145, ipaul@gcd.com).

Respectfully submitted,

Georgia M. Decker, MS, RN, CS-ANP, AOCN®
President

Pearl Moore, RN, MN, FAAN
Chief Executive Officer

Bayer HealthCare

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October 10, 2006

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
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RE: CMS-1506-P: Medicare: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Bayer HealthCare LLC

400 Morgan Lane
West Haven, CT 06516

Phone: 203-812-2000

Dear Dr. McClellan:

Bayer Healthcare LLC ("Bayer") submits the following comments in response to the proposed Hospital Outpatient Prospective Payment System ("OPPS") and CY 2007 Payment Rates (the "Proposed Rule").[1] For more that 100 years, Bayer has produced high-quality drugs and biologics that have helped patients lead healthier lives. We appreciate this opportunity to comment on the Proposed Rule and look forward to working with the Centers for Medicare and Medicaid Services ("CMS") throughout 2007 to improve the health of Medicare beneficiaries.

Bayer presents the following comments for consideration regarding the proposed payment for drugs, biologicals, and radiopharmaceuticals without pass-through status that are not packaged. We are particularly concerned about the proposal to pay for all specified covered outpatient drugs ("SCODs") at 105 percent of the average sales price ("ASP"). The proposal, in our view, is simply not consistent with the requirements of the Medicare Modernization

[1] 71 Fed. Reg. 49506 (Aug. 23, 2006).

Act ("MMA").[2] We thank you in advance for consideration of our comments on this issue.

In CY 2006 and subsequent years, section 1833(t)(14)(A)(iii) of the Social Security Act (the "Act") requires that payment for SCODs be equal to the average acquisition cost of the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office. We appreciate that the Agency has concluded that for CY 2007, on average, hospitals could acquire a range of drugs at 105 percent of ASP. However, we question the legality and analytical strength of this proposal.

We are deeply concerned about the Agency's application of Section 1833(t)(14)(A)(iii) and find it to be inconsistent with a plain reading of the statute. The Act does not contemplate the calculation of ambulatory payment classification ("APC") payment rates on a composite basis. Section 1833(t)(14) refers to the payment for "a specified covered outpatient drug" covered as part of a hospital outpatient department service.[3] The statute goes on to define the amount of payment as "the average acquisition cost for the drug."[4] The plain language of the Act reveals that drug APC payment rates must be determined on an individualized basis, with references to "a . . . drug" and "the drug" in the singular form.

The courts have been clear in a series of cases that the plain language of a statute must be honored by a regulatory agency.[5] Regulatory

[2] Pub. L. No. 108-173 (2003).
[3] Emphasis added.
[4] *Id.*
[5] "[N]o matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161, 120 S.Ct. 1291, 1315 (2000) (internal quotations and citations omitted). Accordingly, a regulatory agency "must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 104 S.Ct. 2778, 2781 (1984) (footnote omitted). Indeed, a regulatory agency "has no power to correct flaws that it perceives in the statute it is empowered to administer.

agencies do not have the discretion to deviate from the plain language of a statute.

Even assuming the accuracy of the Agency's conclusion that, on average, hospitals may acquire all 500 drugs and biologicals at 105 percent of ASP (which we question below), that fact is irrelevant in determining the drug APC payment rates prescribed by the Act. Congress could have required CMS to take into account the average price at which hospitals acquire all drugs. It did not, and we can find no evidence that Congress intended that CMS determine drug APC payments rates on anything other than a drug-by-drug basis.

In addition to our legal concerns, we are apprehensive regarding the analysis, which fails, we fear, to differentiate between costs and charges. It appears that CMS is operating based on the premise that charges are adequate to cover acquisition costs and related drug costs. We question the accuracy of this assumption and challenge the validity of the Medicare Payment Advisory Commission ("MedPAC") information cited to corroborate this assertion.[6] On their face, MedPAC's conclusions appear unsound. It is disturbing that those conclusions seem to be based on a number of informal consultations and not on statistically significant survey results that reflect charging practices. Given the concerns about the nature of the data used and the methodology employed, we fear that this proposal, when applied to individual drugs, provides no assurance that the payment covers the acquisition cost for the drug and related costs and is, therefore, arbitrary and capricious.

Its rulemaking power is limited to adopting regulations to carry into effect the will of Congress as expressed in the statute." *Board of Governors of Federal Reserve System v. Dimension Financial Corp.*, 474 U.S. 361, 374, 106 S.Ct. 681, 689 (1986) (footnote omitted). However, even putting this point to the side, we see no flaws, perceived or otherwise, with the plain language of the MMA provision. It is not a flawed policy to require, as Congress did, that costs be determined on a drug by drug basis. Indeed, this is the best means of ensuring appropriate payment.

[6] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, Ch 6, Payment for Pharmacy Handling Costs in Hospital Outpatient Departments," 141 (Jun. 2005).

We are also troubled by the Agency's reasoning, which appears to conclude that a payment rate determined by reducing charges to costs would be appropriate to cover handling and acquisition costs simply because hospitals set charges for drugs high enough to reflect handling costs and acquisition costs. At best, we believe CMS' analysis suggests that payment at charges may be adequate.

We also have reservations about the proposed methodology for determining the average reimbursement from charges reduced to costs. For instance, in stating that 105 percent of ASP for the fourth quarter 2005 was equal to the mean costs derived from the CY 2005 hospital claims data, the Proposed Rule did not specify whether CMS considered all CY 2005 claims data or merely the data for the fourth quarter of that year. Given the well-established concerns that have been articulated with CMS' OPPS methodology generally and the accuracy of the cost data used, we do not believe that the Agency supports its methodology by pointing to the OPPS claims data. Significantly, Congress has directed the Agency to use data beyond the OPPS claims data in determining SCOD costs.

In addition to the legal and analytical issues presented, we believe that the proposed reduction reflects a poor policy. This policy can only be implemented at the expense of beneficiaries treated with drugs that hospitals cannot acquire consistent with the proposed reimbursement. Using an average, composite approach necessarily means that some hospitals will be forced to lose money each time some drugs are administered. We fear that this will discourage hospitals from continuing to administer some products, eroding beneficiary access to important therapies. In revising drug payment rates under the MMA, we believe that Congress intended to account for the acquisition price of drugs more accurately. We do not believe that Congress had any intention of impinging on beneficiary access in doing so. As such, we urge you to reconsider this specious proposal.

We appreciate your thorough review of our concerns regarding the proposal to pay for SCODs at 105 percent of ASP, and we urge you to proceed with caution as you consider the legal and policy issues involved.

Thank you again for your consideration of the above comments on the Proposed Rule. Bayer looks forward to continuing to work with you to improve the health of Medicare beneficiaries and thanks you in advance for your time.

Sincerely,

Mr. Jeffrey M. Greenman
Bayer HealthCare LLC
General Counsel and Secretary

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Roche

October 10, 2006

BY HAND DELIVERY AND EMAIL
www.cms.hhs.gov/regulations/eRulemaking

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Re: CMS-1506-P; Comments Regarding The Hospital Prospective Payment System and CY 2007 Payment Rates

Dear Administrator McClellan:

Hoffmann-La Roche Inc. ("Roche") appreciates this opportunity to submit comments regarding proposed rule *Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates.*[1] As a company dedicated to bringing innovative, effective, high quality therapies to patients, Roche supports updating payment policies under the outpatient prospective payment system (the "OPPS") to reimburse the provision of important services in a fair and equitable manner. Roche also supports updating payment policies under the OPPS to provide Medicare beneficiaries with access to the most appropriate therapies. While we generally endorse the changes presented in the proposed rule, we have some recommendations that we request that you consider in developing the final 2007 rule. Specifically:

- Roche disagrees with the Agency's[2] proposal to pay for the acquisition and overhead costs of separately paid drugs[3] at a combined rate of the average sales price ("ASP"), plus 5 percent. We believe that the reduction of payments that is proposed for separately payable drugs and biologicals will unfairly burden hospitals.

- Roche asks CMS to closely monitor the impact of policy changes, in particular the application of reimbursement from the competitive acquisition program ("CAP") to the OPPS setting, and not make modifications contrary to the original intent of the pass-through program. Transitional pass-through payment status is a critical reimbursement incentive that encourages appropriate use of new innovative drugs.

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[1] 71 Fed. Reg. 49506 (August 23, 2006)

[2] The term Agency refers to the Centers for Medicare and Medicaid Services or CMS.

[3] The term "drugs" refers to drugs and biologicals.

Hoffmann-La Roche Inc. 1425 K Street, N.W. Suite 650 Washington, D.C. 20005 Federal Government Affairs Tel. 202-408-0090 Fax 202-408-1750

- We ask CMS to expand its guidance on codes with Comment Indicator "NI". Roche understands the need to "flag" new HCPCS codes with indicators that have been assigned to new technology. We would like CMS to clarify the length of time allowed for public comment for HCPCS codes with Comment Indicator "NI", and at what point the indicator will be removed.

A more detailed explanation of these comments and concerns is set forth below.

I. Proposed Payment for Specified Covered Outpatient Drugs (SCOD)

The Social Security Act (SSA) requires that payment for SCODs, or drugs for which a separate Ambulatory Payment Classification (APC) has been established and that is either a radiopharmaceutical agent or is a drug or biological for which pass-through payment was made on or before December 31, 2002 (subject to certain exceptions), in CY 2006 and subsequent years, be equal to the "average acquisition cost for the drug for that year . . . as determined by the Secretary," subject to any adjustment for overhead costs and taking into account the GAO hospital acquisition cost surveys for CYs 2004 and 2005. If hospital acquisition cost data are not available, payment must equal "the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph."

Although last year CMS paid for SCODs at ASP+6 percent, this year CMS proposes paying for them at ASP+5 percent. To arrive at this figure, CMS compared two sources of data - - ASP data from the fourth quarter of CY 2005 and mean "costs [of drugs] derived from the CY 2005 hospital claims data." CMS maintains that its data analysis demonstrates that using mean costs to set SCOD payment rates for drugs would be "equivalent to basing their payment rates, on average, at ASP+5 percent." CMS then asserts that hospitals set charges for drugs high enough to reflect their pharmacy handling costs as well as their acquisition costs. CMS further states that, therefore, payment for drugs and pharmacy overhead at a combined ASP +5 percent rate would serve as the best proxy for the combined acquisition and overhead costs of each of these products.

We are concerned that there are flaws in this analysis. First, the analysis does not distinguish costs from charges. CMS assumes that hospitals set charges at a level that is high enough to "reflect" handling and acquisition costs, but does not cite any reliable data to support this premise. In this regard, CMS' assumption is based on a MedPAC analysis[4] that did not clearly distinguish charges and costs. Second, CMS does not adequately explain how it determined its average reimbursement of ASP+5 percent from charges reduced to costs. For instance, CMS suggests that ASP+5 percent for the fourth quarter 2005 was equal to the mean "costs [of drugs] derived from the CY 2005 hospital claims data," but does not specify whether all CY 2005 or only fourth quarter 2005 claims data were considered. CMS also does not discuss the degree to which ASP+5 percent matches costs determined from charges across a range of drugs.

[4] The Medicare Payment Advisory Committee Report, "Report to the Congress" March 2006.

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Given these analytical flaws, we are concerned that this proposed shift to payment of ASP+5 percent may not adequately compensate for acquisition and handling costs and will impede beneficiary access to important drug therapies. Implementing the proposed ASP+5 percent change introduces complexities in the CMS drug payment provisions with no clear benefit in terms of accuracy of payment. For these reasons, we suggest that CMS maintain the current rate-setting methodology for most separately paid OPPS drugs and biologicals, and maintain payment at ASP+6 percent.

II. Pass-Through Drugs

CMS proposes to continue to reimburse pass-through drugs and biological products at ASP+6 percent, except for drugs that also are included in the Competitive Acquisition Program (CAP), which will be reimbursed at the CAP rate. We support CMS's decision to continue reimbursement for non-CAP covered drugs and biologicals that are eligible for pass-through payment at ASP+6 percent. This enforces CMS's intentions of proper billing code adoption and appropriate reimbursement for drugs entering the market.

However, although we appreciate CMS's commitment to consistent payment practices; we are concerned in regard to the proposed rate-setting for these drugs that may also be included under the CAP list. CMS states that drugs and biologicals with pass-through status which are covered under the CAP will be reimbursed at the "amounts determined under the competitive acquisition program."[5] We ask CMS to clarify that, as required by the statute, it will base payment for these drugs and biologicals on the amount by which "the average price for the drug or biological for all competitive acquisition areas and year established under [Section 1847B] as calculated and adjusted by the Secretary for purposes of this paragraph" exceeds the portion of the applicable Medicare OPD fee schedule associated with the drug or biological.[6] Importantly, the statute directs the Secretary to adjust the average CAP prices to account for the purposes of the pass-through program, which is to provide appropriate incentives for the development of innovative therapies for Medicare beneficiaries. The statute also requires the Secretary to consider pass-through payments on an individual drug-by-drug basis, not an aggregate basis as the Proposed Rule suggests. We believe that setting the payment amount for pass-through drugs and biologicals at the CAP negotiated amount would be inconsistent with the statutory language and with the purpose of the pass-through program. It also could have unintended consequences for the prices proposed and negotiated in the CAP program.

We also encourage CMS to set the payment amount for pass-through drugs and biologicals at WAC+6 percent until an ASP payment rate or an individual payment rate under the CAP is set. This payment metric will ensure that these drugs are paid adequately and will thus be accessible to Medicare beneficiaries who need these therapies in the hospital outpatient setting.

On a separate note, we would like CMS to confirm in the Final Rule that once a permanent J-code or temporary Q-code is assigned to a pass-through drug and its corresponding temporary C-

[5] Fed. Reg. at 49581

[6] 42 U.S.C. § 1395l(t)(6)(D)(i).

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code is deleted, that the J-code or temporary Q-code remains on the pass-through status list until its expiration date after a minimum of two years, up to three years.

III. Estimated Transitional Pass-Through Spending

As noted in the proposed rule, the applicable percentage of total payments under OPPS which results in the pass-through payment for drugs, biologicals, radiopharmaceuticals and categories of devices has decreased each year since CY 2003, from 2.5 percent to the now proposed 1.87 percent. We are concerned about this downward trend in support for innovative therapies. The pass-through system provides essential compensation to hospitals for costs not covered in the APC payments, and reductions in the payment inevitably cause a slower uptake of new drugs and devices, which may lead to suboptimal care for Medicare beneficiaries. We urge CMS to reconsider the proposed 1.87 percent and maintain a more appropriate payment level.

IV. Comment Indicator "NI"

As has been done in the past, CMS proposes to continue to assign Comment Indicator "NI" to HCPCS codes indicating to the public an interim payment amount has been assigned. Roche understands the need to "flag" new HCPCS codes with indicators that have been assigned to new technologies, but we ask CMS to clarify the length of time allowed for public comment for HCPCS codes with Comment Indicator "NI", and at exactly what point the "NI" designation will be removed.

V. Conclusion

We appreciate the opportunity to provide comments and recommendations. We hope that our suggestions will assist CMS in its mission to provide Medicare beneficiaries with access to high quality therapies. Thank you for your attention to this matter. Please feel free to contact me if you have any questions or need additional information.

Respectfully submitted,

Evan T Morris

Evan Morris
Executive Director, Federal Government Affairs

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October 10, 2006

VIA HAND DELIVERY

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P - Medicare Program; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List

Dear Dr. McClellan:

On behalf of the Surgery Division of HealthSouth Corporation, I am pleased to submit the following comments regarding Section XVII of the proposed rule that would make revisions to policies affecting ambulatory surgical center (ASC) procedures effective January 1, 2007. 71 Fed. Reg. 49505 (August 23, 2006). The tremendous amount of work put forth by the Centers for Medicare and Medicaid Services (CMS) in issuing this proposed rule is appreciated.

With interests in 148 ASCs in 36 states, HealthSouth is the one of the largest operators of ASCs in the United States. ASCs offer a convenient, safe environment characterized by superior care, which is highly valued by both beneficiaries and their physicians.

I. Proposed ASC List Update Effective for Services Furnished On or After January 1, 2007

A. Criteria for Additions to or Deletions from the ASC List

We commend CMS for proposing to update the ASC list for CY 2007. However, we note that the criteria used to revise the list of procedures that may be reimbursed when performed in an ASC remain unchanged. The unduly restrictive nature of the site of service volume criteria and time limits currently in place has been commented upon extensively by stakeholders in the ASC community, and noted by MedPAC in their March 2004 congressional report. Delaying implementation of these reforms has two principal outcomes: beneficiary access to ASC services will continue to be limited unnecessarily in CY 2007, and the Medicare program and its beneficiaries will continue to bear higher costs than necessary for many of the excluded outpatient surgeries and procedures.

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However, we are pleased CMS has acknowledged these proscriptions are no longer appropriate and has proposed revised criteria for CY 2008. Our specific comments regarding these proposed revisions will be forthcoming in the near future.

B. Procedures Proposed for Addition to the ASC List

We are appreciative of CMS's proposal to update the ASC list for 2007. These regular updates help ensure Medicare beneficiaries have access to more of the services ASCs routinely and safely offer to non-Medicare patients.

All of the proposed additions are clinically appropriate. However, we are concerned the payment group assignments for certain of the procedures will result in reimbursement at a level insufficient to cover the cost of performing the procedure.

We are concerned about the payment group assignment for CPT code 22522, which describes percutaneous vertebroplasty performed at additional levels. The proposed payment group assignment is a Group 1 ($333). The cost of the kit used at each level varies from $700 to $1400, depending on the supplier (Stryker, Arthrocare). Therefore, the proposed level of reimbursement would not be sufficient to cover supply costs for the procedure. In light of this, we recommend revising the payment group assignment to a Group 9 ($1339). Because this particular code is an add-on code, and therefore will always be subject to multiple procedure payment reduction, assignment to payment Group 9 will only cover supply costs. CMS has established reimbursement at $1542.47 for this service under OPPS. Given that this reimbursement is derived from cost data, we believe it serves as a reliable indicator of the cost of providing this service.

We are also concerned about CPT codes 37205 and 37206, which describe transcatheter placement of an intravascular stent. The proposed payment group assignments are Group 9 ($1339) and Group 1 ($333), respectively. The cost of the intravascular stent averages $1725 (see CMS's 2005 file which calculates device related percentages for APC 0229), which exceeds the current maximum Group 9 reimbursement level. However, we believe the stent should be eligible for separate reimbursement under the current ASC payment methodology. Significantly, because there is no specific Level II HCPCS code that describes this stent, this device would have to be reported using L8699. ASCs experience considerable difficulty securing reimbursement from Medicare carriers for devices reported using L8699. We believe this obstacle could be overcome if CMS specifically advised all Medicare carriers that a stent is not a supply and therefore eligible for separate reimbursement.

Despite the challenges to adequate reimbursement for the procedures discussed above, we believe CMS should add the procedures to the list. All are clinically appropriate services and adding them will allow those patients whose private health plans look to CMS's ASC list for coverage decisions to access these procedures in the ASC setting.

C. Suggested Additions Not Accepted

1. Procedures suggested for addition, but not accepted because they are commonly performed in physician offices

Many procedures that were suggested through public comment for addition were rejected on the basis that they are commonly performed in physician offices. CMS has determined if a procedure is performed 50 percent or more of the time in the office setting, it is inappropriate for addition to the ASC list. CMS relies on Part B claims data when determining the frequency with which procedures are performed in various settings. However, it has been well established by the OIG that site of service reporting on physician claims can be a highly unreliable indicator of the actual site of service; significant error rates (80 % and higher in some cases) for selected services have been reported. Given the probability of significant flaws in the data CMS uses to make these decisions, we do not believe reliance on this data is appropriate.

There is no evidence that including procedures on the ASC list that are frequently performed in the office setting leads to overutilization in the ASC setting. There are several services that have been on the ASC list since its inception although they technically qualify as office procedures based on the current criteria. CMS has acknowledged that inclusion of these services on the ASC list - although commonly performed in the physician office - has not resulted in excessive utilization of ASCs (70 Fed. Reg. at 23696). CMS stated, "Consistently, the physician office is the predominant service setting even though the procedures were included on the ASC list." CMS subsequently concluded "that the relative stability of the utilization and site of service is evidence that the inclusion of the codes on the ASC list has not influenced the physician's selection of setting for performance of the procedures and provides strong evidence that there is a small but consistent population of beneficiaries for whom the ASC setting is the most appropriate for these procedures."

Most of the procedures CMS has indicated it will not add to the ASC list are typically performed as secondary procedures for non-Medicare beneficiaries. Failure to add the requested procedures because they are commonly performed in the office setting deprives both the Medicare program and its beneficiaries of the efficiencies of care and added affordability that other patients enjoy as a result of use of the ASC setting.

For example, there are patients requiring endoscopic evaluation for reanastomosis following a partial colectomy with colostomy, in which both a colonoscopy via stoma (CPT code 44388) and flexible sigmoidoscopy (CPT code 45330) are needed for a complete evaluation. Non-Medicare patients can have both procedures performed at the same session in an ASC. This is not the case for Medicare beneficiaries. While the colonoscopy via stoma (CPT code 44388) is an ASC list procedure, the flexible sigmoidoscopy (CPT code 45330) is not. In order to have both procedures performed concurrently as an outpatient, the Medicare beneficiary must be seen at the HOPD.

Not only does this policy lead the Medicare program to miss opportunities for efficiencies of care, it also leads to significant additional expense to both the program and its beneficiaries. Having both these procedures performed in an HOPD costs the Medicare program $649.44, with a minimum beneficiary copayment of $129.89. If the Medicare program would allow the flexible sigmoidoscopy in the ASC setting, assuming a Group 1 payment assignment,

the cost of the two procedures together would be $458.82, with a beneficiary copayment of $91.76.

As is the case with many procedures commonly performed in the physician office, there are certain patients whose medical condition requires a procedure be performed in a facility setting. In the case of flexible sigmoidoscopy, this would include patients with anal stenosis and anastomotic strictures, who require sedation for a comfortable and safe examination. Current CMS policy does not allow these patients to access care in the more affordable ASC setting.

Though certain procedures are commonly performed in the office setting, the physician should not be restricted in the exercise of professional judgment when determining the most appropriate site of service. Hospital outpatient departments are not restricted in their ability to serve as the site of service when the physician determines the office setting will not meet the needs of the patient. When medically necessary, ASCs should also be an option for those Medicare beneficiaries requiring the services of a facility for appropriate and safe care. Therefore, we urge CMS to reconsider its decision to forgo adding the services presented in Table 42 (71 Fed. Reg. at 49629) because they are predominantly performed in the physician office.

We believe all the CPT codes presented in Table 42 should be added to the ASC list for CY 2007.

2. Procedures suggested for addition, but not accepted because CMS states they do not meet current clinical criteria

Table 43 of this proposed rule presents procedures that commenters suggested for addition, but that CMS is not adding because they do not meet current clinical criteria (71 Fed. Reg. at 49629). The specific clinical criteria that form the basis for rejecting each of these procedures are not stated.

We believe all of the procedures discussed below are clinically appropriate and request CMS add these procedures to the ASC list for CY 2007.

a. Osteochondral arthroscopic grafting

Several commenters suggested the addition of CPT codes 29866 and 29867 describing arthroscopic knee procedures in which osteochondral autografts or allografts are placed. These procedures meet the current clinical criteria for addition to the ASC list. Surgery and anesthesia times are under 90 minutes, and recovery times generally average four hours. As with other arthroscopic knee procedures, blood loss is minimal.

b. Laparoscopic cholecystectomy

A number of commenters suggested the addition of CPT codes 47562, 47563, and 47564 describing laparoscopic cholecystectomies. The first laparoscopic cholecystectomy performed in the United States was performed at an ambulatory surgical center in 1988. These procedures are

commonly performed for non-Medicare patients in the ASC setting. CMS data shows these procedures are routinely performed on an outpatient basis in Medicare patients; Medicare volume data shows these procedures as being performed on an outpatient basis 51%, 48% and 24% of the time, respectively.

CMS indicated it was not including these procedures on the ASC list because an overnight stay would often be required for Medicare patients. In light of the volume data presented above, we believe many Medicare beneficiaries are having laparoscopic cholecystectomies performed without an overnight stay in the HOPD. We recognize an ASC will not be the appropriate site for all Medicare beneficiaries. However, by not adding these procedures to the ASC list, CMS effectively denies all Medicare beneficiaries access to the ASC.

CMS has also rejected the procedures on the basis of "a substantial risk that the laparoscopic procedure will not be successful and that an open procedure will have to be performed instead." (70 Fed. Reg. at 23700). CMS stated that if an open procedure were required, the patient would have to be transported to the hospital for the procedure.

It is unclear what clinical data was used to determine "substantial risk." The literature contains many studies of laparoscopic cholecystectomy in a variety of surgical settings, with different patient populations and differing levels of patient acuity. We are aware of just one recent study which exclusively evaluated the outcomes of outpatient ambulatory laparoscopic cholecystectomy in the United States, as reported by Lau and Brooks in the World Journal of Surgery in September of 2002. In this retrospective analysis of 200 procedures, no patient required conversion to an open cholecystectomy. While conversion to an open cholecystectomy is possible, it is not common. In fact, based on available data, the risk appears to be slight rather than substantial.

When determining the site of service for an elective laparoscopic cholecystectomy, the surgeon may be rigorous in the application of patient selection criteria, thereby minimizing the risk of a subsequent conversion to an open procedure. This is not the case when the patient requires an emergent procedure. It is true that laparoscopic cholecystectomies are converted to open procedures at a rate of 5 to 10 percent in national studies of *hospital* discharge data (Livingston and Rege, American Journal of Surgery, September 2004). However, these conversion rates reflect procedures performed in the hospital setting, in unselected patient populations, and under both emergent and elective conditions.

Finally, it is important to note that if the laparoscopic approach is unsuccessful in the ASC setting, the patient does not have to be transported to the hospital for the open procedure. Generally, the laparoscopic procedure can be converted to an open procedure and completed at the ASC. The patient is then transported to the hospital following completion of the procedure and postoperative stabilization. Again, the application of patient selection criteria would make such conversions a rare occurrence.

c. Lumbar disc decompression

CPT code 63030 describes lumbar disc decompression. As a result of today's minimally invasive approaches, more of these procedures are being safely and successfully performed in the outpatient setting. Anesthesia and operating times are less than 90 minutes. Though recovery times can extend beyond four hours, these procedures can be performed without an overnight stay and with a home visit for follow-up. We believe the continued imposition of specific operating and recovery time limits is unduly restrictive, a point which has been recognized by MedPAC and by CMS itself in the past. Patients with private insurance routinely have these procedures performed in the ASC setting and therefore we urge CMS to allow Medicare patients to access these procedures in the ASC setting as well.

D. Other Appropriate Additions Not Addressed in the Proposed Rule

In this notice of proposed rulemaking, CMS proposes to add CPT codes 13102, 13122 and 13133 to the ASC list effective January 1, 2007. CPT code 13153 is also included in this series of codes and describes complex repair of the eyelids, nose, ears and/or lips in excess of 7.5 cm in size. However, this code is not currently on the ASC list, nor has CMS proposed its addition. By definition, complex repairs require time-consuming interventions such as scar revision, debridement, and extensive undermining. Work on the areas of the face described by this CPT code requires meticulous attention to detail for optimal outcomes, and a repair of this magnitude adds to the complexity of the procedure. Time in the operating room may be significantly extended by each additional 5 cm requiring this type of repair. All the other codes in this series, 13150-13152, are currently on the ASC list and assigned to payment group 3. Excluding more extensive repairs from the ASC setting is not consistent. Based its similarity to the other proposed additions, CPT code 13153 should also be added to the ASC list effective January 1, 2007.

CPT code 43257, for thermal treatment of the lower esophageal sphincter during EGD is another appropriate addition to the ASC list. We believe that this endoscopic treatment for gastroesophageal reflux disease meets all the current clinical criteria and should be added effective January 1, 2007.

CMS should also add G0289, which describes knee arthroscopy for removal of a loose body, foreign body, or chondroplasty concurrent with another surgical knee arthroscopy in a different compartment of the same knee. CMS guidelines stipulate that G0289 may only be reported when the procedures described by this code require at least an additional 15 minutes of operating time. The use of this amount of additional operating room time – with attendant staff, equipment and supplies – should be recognized for additional reimbursement. Therefore we urge CMS to add G0289 to the ASC list effective January 1, 2007.

II. Implementation of Section 5103 of Pub. L. 109-171 (DRA)

Given the absence of a correction notice, we are concerned to note CPT codes 19290 and 19291, which describe preoperative placement of needle wire in the breast, are not listed in Addendum AA of the proposed rule as ASC list procedures for 2007. Both procedures are currently on the ASC list as Group 1 procedures. We believe this is a typographical error.

However, if these CPT codes were omitted intentionally, were they removed from the ASC list because they are not separately reimbursed under OPPS?

If this is the case, we do not believe these deletions are a correct application of the DRA's statutory requirement. The intent of Section 5103 was to prevent ASCs being paid more than hospitals for providing the same services. There is nothing in the statute or its legislative history to indicate Congress intended to deny ASC coverage for procedures packaged under a totally different payment system. The DRA payment cap is meant to apply only to those procedures for which there is both an ASC "standard overhead amount" and an OPPS "fee schedule amount" for purposes of comparison. If, as with 19290 and 19291, there is no OPPS fee schedule amount because the service is packaged into the APC payment, then there is no basis for making a valid payment comparison and the DRA cap does not apply.

Further, 19290 and 19291 are pre-operative localization procedures, and since the ASC payment rate for the subsequent surgery was calculated assuming separate payment for 19290 and 19291, excluding these services from the ASC list without adjusting payment for the operative procedure upward would be inappropriate.

Therefore, we believe CPT codes 19290 and 19291 should remain on the ASC list for 2007.

III. Proposal to Modify the Current ASC Process for Adjusting Payment for New Technology Intraocular Lenses

We are supportive of CMS's plans to streamline the process of recognizing intraocular lenses that qualify for a payment adjustment as a new technology intraocular lens (NTIOL). We also agree it would be more efficient to incorporate this into the annual update of ASC rates for the following calendar year. Including a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published would be very helpful, but we do not believe the proposed 30 day comment period is sufficient. Given the highly technical nature of NTIOLs, we believe a 60 day comment period would be more appropriate.

While we also generally agree with the list of examples of superior outcomes provided by CMS, we believe any revision of §416.195 should make it clear that these are strictly examples. Given the rapid pace of technological advances, it would be unfortunate if the revised language did not provide sufficient flexibility to accommodate future innovations because they are not specifically outlined as a superior outcome. Therefore we suggest §416.195(a)(4) be modified to read, "Evidence demonstrated that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Examples of superior outcomes include, but are not limited to:", to be followed by the currently listed outcomes (i) through (vi).

* * * * *

Thank you for considering our comments. If you have any questions or need additional information, we would be happy to assist you.

Sincerely,

Kimberly L. Wood

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September 5, 2006

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Centers for Medicare and Medicaid Services
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Room 445-G
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200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Comments to The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (CMS-1506-P)

Dear Administrator McClellan,

Novartis appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (CMS-1506-P) proposed rule (hereafter referred to as the "proposed rule"). Novartis is a leading global pharmaceutical manufacturer that is dedicated to the discovery, development, and marketing of innovative products to cure diseases, to ease suffering, and to enhance the quality of life. Novartis manufacturers both traditional pharmaceuticals and physician administered drugs and biologics, many of which are utilized for Medicare beneficiaries in the hospital outpatient setting.

Pass-through Drugs

We support CMS' decision to continue its policy of paying for pass-through products under ASP + 6% with quarterly updates, and we also recognize the additional MMA requirement of paying for these products under the rate determined under the Competitive Acquisition Program (CAP). Our concern is in the rare case where the CAP rate is actually higher than ASP + 6%, as is currently the case for several drugs. Although this does not impact the two products identified under this proposed rule, we would suggest that the agency instead phrase the rule to reflect that CMS will pay pass-through drugs at ASP + 6% or the CAP rate, whichever is less. This would therefore not create any reimbursement differentials in the marketplace.

OPPS: Non Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

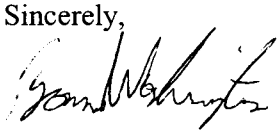
In the proposed rule, CMS continues its policy of setting payments for separately paid "specific covered drugs and biologicals" (SCODs), as defined in the Medicare Modernization Act (MMA), based on mean cost findings for each product, which in the case of this proposed rule equates to ASP +5%. The Social Security Act (SSA) requires that payment for SCODs in CY 2006 and subsequent years be equal to the "average acquisition cost for the drug for that year . . . as determined by the Secretary," subject to any adjustment for overhead costs and taking into

account the GAO hospital acquisition cost surveys for CYs 2004 and 2005.[1] We have some reservations surrounding the methodology by which CMS arrived at the pharmacy overhead cost, which led to the SCOD payment rate being set at ASP + 5%. CMS states that it used CY 2005 mean unit cost data to come up with the 5% add-on payment but does not provide any detail on the methodology it used.

In addition, CMS appears to be ignoring the recommendation of its own APC Panel. In the APC Panel's March 1-2, 2006, report (recommendation #40) it states, CMS should "work with appropriate associations to study how to measure pharmacy overhead costs." There is no indication that CMS did involve external stakeholders in their analysis. A solid understanding and appropriate reimbursement of pharmacy overhead costs is especially essential in specialties like oncology where the preparation, storage, transport, and disposal costs can be significant. We encourage CMS to hold on changing to an ASP+5% payment rate until a more thorough analysis of pharmacy overhead costs can be done in association with appropriate stakeholders.

There also appears to be a discrepancy in that the MedPAC "survey," which CMS utilizes to determine that payments made at charges reduced to costs would be adequate, does not properly construe costs and charges. MedPAC stated that "hospital officials and others told MedPAC staff that hospitals build handling costs for drugs, biologicals, and radiopharmaceuticals into the charges for the products themselves as part of the markup over costs."[2] If true, this would assume that handling costs are already reflected in the hospital charges that CMS utilized. For these reasons and others, we believe that a more thorough and open examination of this issue should be held before any payment changes are proposed.

Sincerely,



Bonnie Washington
Vice President, Health Policy
Novartis Pharmaceuticals

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[1] SSA § 1833(t)(14)(A)(iii).
[2] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, Ch 6, Payment for Pharmacy Handling Costs in Hospital Outpatient Departments," 141 (Jun. 2005).

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October 10, 2006

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
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Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List (CMS-1506-P) – Comments on Proposed Polices Affecting Ambulatory Surgical Centers (ASCs) for CY 2007 (Section XVII)

Dear Administrator McClellan:

FASA is pleased to submit these comments on those provisions of the August 23, 2006 Hospital Outpatient Prospective Payment System (OPPS) proposed rule affecting ASC payment in 2007. FASA (until this year officially named the Federated Ambulatory Surgery Association, but recently having adopted as its official name the former acronym) is the nation's largest ASC organization, representing nearly 1,800 ASCs, the professionals who provide care in such centers and the patients who receive high quality and cost-effective ASC services. We are particularly pleased that CMS has continued to meet its commitment to biennial reviews of the Medicare list of covered ASC procedures. Regular updates of the ASC list, as intended by Congress, help promote Medicare beneficiary access to the growing number of procedures that ASCs are routinely and safely performing for their non-Medicare patients. And such access, in turn, improves quality of care and saves money for Medicare and its beneficiaries.

Given CMS's decision to work within the current regulatory framework in updating the ASC list and Medicare payment rates for 2007, we offer comments on the following provisions of the proposed rule: (1) procedures proposed for addition to the ASC list for 2007 (Section XVII.B.3); (2) procedures that should be added to the ASC list for 2007 (Section XVII.B.4); (3) payment group adjustments (Section XVII.B.6); and (4) issues related to implementation of the statutory cap on ASC payments mandated by the Deficit Reduction Act of 2005 (DRA) (Section XVII.D). We will be submitting separate comments on the proposed revised ASC payment system for 2008.

1. Procedures Proposed for Addition to the ASC List (Section XVII.B.3)

FASA supports CMS's decision to add 14 procedures to the Medicare ASC list for 2007. For non-Medicare patients, many of these procedures (listed at Table 41 of the proposed rule) have been safely and efficiently performed in ASCs for several years. By adding these procedures to the ASC list, CMS continues to expand Medicare beneficiary access to high quality and cost-effective surgical services.

Of course, given the proven quality, convenience and cost benefits of ASCs, we would have liked to have seen more rapid expansion of Medicare beneficiary access to ASC services. Indeed, with the vast expansion of procedures performed in a variety of outpatient settings, as well as the demonstrated quality of care that ASCs have provided to Medicare patients for more than 20 years and to non-Medicare patients for more than 30 years, FASA has long contended that a limited list of ASC-covered procedures no longer serves a beneficial purpose and should be abandoned. Thus, we are gratified to see that the revised ASC payment system proposed for 2008 will at last eliminate Medicare's reliance on an ASC list and significantly expand coverage of ASC services.

While all of the proposed additions to the ASC list for 2007 clearly are clinically appropriate, we are concerned that the payment group assignments for the following new procedures are not adequate to cover their costs and, thus, will continue to deny Medicare beneficiaries access to their performance in ASCs:

- Percutaneous vertebroplasty performed at additional levels (CPT 22522). While the proposed payment group assignment is Group 1 ($333), the cost of the kit used at each level varies from $700 to $1400, depending on the supplier (i.e., Stryker or Arthrocare). Therefore, the proposed level of reimbursement would not be sufficient to cover supply costs for the procedure. In light of this, we recommend revising the payment group assignment to Group 9 ($1,339). Because this is an add-on code, and thus always subject to multiple procedure payment reduction, even assignment to payment Group 9 will only cover supply costs.

- Transcatheter placement of an intravascular stent(s) (CPT 37205 and 37206). The proposed payment group assignments are Group 9 ($1,339) for 37205 and Group 1 ($333) for 37206. To look at one measure of costs, the OPPS device-related percentages for APC 0229 from 2005 indicate that average cost of the intravascular stent is approximately $1,725, which exceeds the current maximum Group 9 reimbursement level. Therefore, no level of reimbursement currently available to ASCs would be sufficient to cover the device costs for these procedures. Unfortunately, there is no opportunity for ASCs to receive separate reimbursement for the stent. In light of this, we believe ASCs will not be able to cover the costs of performing these procedures under the current reimbursement methodology. However, we still believe CMS should go forward with adding these procedures to the list because they are clinically appropriate services and doing so will allow those patients whose private health plans look to CMS's ASC list for coverage decisions to access these procedures in the ASC setting.

2. Procedures That Should Be Added to the ASC List for 2007 (Section XVII.B.4)

A. Procedures Not Added to the ASC List Because They Are Predominantly Performed in Physician Offices

Table 42 of the proposed rule identifies a number of procedures that were not added to the ASC list because, under the current regulatory criteria, they are predominantly performed in physician offices. The criterion that ASC list procedures not be of a type commonly performed in physician offices was created to prevent the shift of procedures that are safely and routinely performed in physician offices to the more capable ASC setting.

As we have noted in the past, however, the problem with this criterion is that while physicians may safely perform many procedures on healthy Medicare beneficiaries in the office setting, sicker or more frail beneficiaries sometimes require the additional infrastructure and safeguards of an ASC to maximize the probability of a good clinical outcome. In other words, for a given procedure, the appropriate site of service is dependent on the individual patient and his or her specific condition. For a patient whose safety requires general anesthesia or a sterile operating room, if an ASC is not an option, most physicians will elect to perform the procedure at a hospital, typically at greater cost to the Medicare program and to the beneficiary.[1] In addition, many non-ASC list procedures are routinely performed in conjunction with a primary procedure that is on the ASC list. By denying Medicare coverage for these secondary procedures, CMS creates an obstacle to their efficient performance with primary procedures in an ASC setting.

CMS proposes to address these issues in the revised payment system for 2008 by providing ASC coverage for procedures that are commonly and safely performed in the office setting, while limiting payment for those procedures to the Medicare physician fee schedule amount (i.e., the non-facility practice expense component). While that proposal is pending, we believe there is a particularly compelling case for adding the procedures identified in Exhibit A to the ASC list for 2007 so as to promote the ability of physicians to select the site of service they believe is most clinically appropriate for their patients.

B. Procedures Not Added to the ASC List Because They Do Not Meet Current Clinical Criteria

Table 43 of the proposed rule identifies other procedures excluded from the ASC list because they do not meet current clinical criteria. No specific reasons or rationale are provided to support these exclusions, however, other than a general statement that the procedures "either require more than 4 hours of recovery time, or may result in excessive blood loss, etc., making them ineligible for addition to the list of ASC procedures." The failure to identify the specific reasons why particular procedures have been excluded sharply limits our ability, and that of experienced medical experts, to provide meaningful comments on CMS's decisions. To help promote more informed decision making on patient safety issues, FASA believes it is essential that CMS identify the specific criterion that is not met in CMS's view so that knowledgeable commenters are able to address the agency's particular concerns. We believe this will become

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[1] According to study commissioned by FASA, Medicare reimbursement to ASCs in 2005 was, on average, $320 per procedure less than what the program paid hospital outpatient departments for performing the same procedures.

particularly important under the revised ASC payment system, where patient safety issues will play a more central role in Medicare's coverage decisions.

In the past, the most commonly cited clinical reasons for excluding particular procedures from the ASC list have been that the procedures either (1) require more than four hours of recovery time, or (2) are "predominantly" performed in hospital outpatient settings. With regards to the four hour time criterion, it is generally acknowledged to be an obsolete requirement. In fact, it was developed in the early 1980s, along with the 90-minute time limit for surgery, to help define procedures that could be safely performed on an outpatient basis at an ASC. As MedPAC has observed, however, these time requirements are "unnecessarily rigid," particularly given the numerous technological advances that are now standard in the ASC setting,[2] and actually were proposed for deletion in 1998.[3] With the development of short-acting general anesthetics, the length of operating time is totally immaterial in determining whether a procedure is appropriately performed in an ASC. The key question is when is the patient ready to be discharged, not how long the surgery takes. Similarly, with respect to the four-hour limit on recovery time, a number of states have expanded the concept of "ambulatory" over the past 20 years by permitting ASCs to perform procedures requiring stays of up to 24 hours. It is not clear to us why CMS feels compelled to continue applying these obsolete regulatory criteria in evaluating the addition of procedures to the ASC list.

We also have been puzzled by CMS's prior decisions not to add a number of procedures to the ASC list that are "predominantly" or "most often" performed in hospital inpatient settings, especially since the current regulatory standards at 42 C.F.R. § 416.65 state that ASC covered procedures specifically *include* those that are "commonly performed on an inpatient basis in hospitals." In fact, CMS historically did not add procedures to the ASC list unless they were performed at least 20% of the time as hospital inpatient services. We can only presume that this specific requirement has been abandoned by CMS, and that the decisions to not add predominantly inpatient services to the ASC list reflect judgments that those particular procedures are not safely or appropriately performed in ASCs. In many cases, we see no substantial support for such conclusions.

Indeed, while CMS increasingly employs evidenced-based medicine to its coverage decisions, virtually no evidence has been provided to support excluding procedures from the ASC list simply because they are predominantly performed in a hospital inpatient setting. In reaching these conclusions,, CMS seems to presume that a hospital is always the safer and more appropriate site of service for any procedure that involves a risk of complications. We are troubled by that apparent presumption, since we are not aware of any empirical evidence supporting it. We also are troubled by the fact that CMS seemingly does not consult outside medical experts with ASC experience when evaluating the safety of ASC procedures. We believe CMS and the Medicare program would benefit greatly from a more evidence-based and collaborative approach to the coverage of ASC procedures. FASA continues to be available to assist CMS in identifying independent medical experts in the ASC industry to collaborate with CMS on patient safety issues.

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[2] MedPAC Report to Congress: Medicare Payment Policy (March 2004) at 199.

[3] 63 Fed. Reg. 32289, 32298 (Jun. 12, 1998) ("[w]e propose to remove the time limits on operating, anesthesia, and recovery time that are currently spelled out in § 416.65(b)(1) and (2)").

Pending implementation of the revised ASC payment system, FASA urges CMS to reconsider adding a number of procedures to the ASC list that we believe can be safely and appropriately performed in ASCs. Our comments on specific procedures are provided at Exhibit B. In some cases, we believe these procedures meet the current regulatory criteria for addition to the list. With many others, CMS again acknowledges that the current criteria are obsolete by proposing to cover the performance of these procedures in ASCs beginning in 2008. We see no reason to delay coverage of these procedures, while moving forward with their addition to the ASC list for 2007 will offer Medicare beneficiaries more options, enhance their access to care and reduce Medicare program costs.

3. Payment Group Adjustments (Section XVII.B.6)

FASA commends CMS for its decision to adjust the payment groups for the following procedures added to the ASC list in 2005:

- Placement of brachytherapy catheters following partial mastectomy (CPT 19298), from Group 1 to Group 9
- Endovenous ablation therapy (CPT 36475-36479), from Group 3 to Group 9
- Hemorrhoidopexy by stapling (CPT 46947), from Group 3 to Group 7
- Hysteroscopy with fallopian tube cannulation (CPT 58565), from Group 4 to Group 9

As is apparent from the significant upward adjustment in payment groups, we agree that the initial rates for these procedures were so low as to effectively deny Medicare beneficiaries access to their performance in ASCs.

We also note an apparent error in Addendum AA of the proposed rule, which identifies codes 36475-36479 as Group 8 procedures. Since Group 8 is an ophthalmology-related payment group, we presume this is a mistake and, as indicated on page 49630, these procedures are in fact assigned to Group 9.

4. Implementation of the DRA Payment Cap (Section XVII.D)

In Section 5103 of the DRA (Pub. L. 109-171), Congress imposed a statutory cap on ASC payments at the OPPS payment amount for the same procedures, pending implementation of the revised ASC payment system. We support CMS's manner of implementing this provision as a limit on Medicare payment for certain procedures, rather than changing the underlying ASC group assignments or group payment amounts. As a result, this cap should not affect payment by commercial insurers or managed care organizations that use the Medicare ASC payment groups as the basis for reimbursing ASCs for services provided to their enrollees.

We also question why CPT codes 19290 and 19291 (preoperative placement of needle wire, breast) are not listed in Addendum AA of the proposed rule as ASC list procedures for 2007. Both procedures are currently on the ASC list as Group 1 procedures. We note that under OPPS, 19290 and 19291 are assigned status indicator "N," signifying that they are packaged into the hospital APC rates, and query whether they were removed from the ASC list as a result of application of the DRA payment cap; that is, did CMS remove these procedures from the 2007

ASC list because they are not separately reimbursed under OPPS? If so, we do not believe that is a correct application of DRA's statutory requirement. Rather, the purpose of Section 5103 was to prevent ASCs from being paid more than hospitals for providing the same services, and there is nothing in the statute or its legislative history to indicate that Congress intended to deny ASC coverage for procedures that are packaged under a totally different payment system. Indeed, it seems obvious that the DRA payment cap is meant to apply only to those procedures for which there is *both* an ASC "standard overhead amount" *and* an OPPS "fee schedule amount" for purposes of comparison. If, as with 19290 and 19291, there is no OPPS fee schedule amount because the service is packaged into the APC payment, then there is no basis for making a valid payment comparison and the DRA cap does not apply. Moreover, 19290 and 19291 are pre-operative procedures, and since the ASC payment rate for the operative procedure was calculated assuming separate payment for the pre-op, excluding 19290 and 19291 from the ASC list now, without adjusting payment for the operative procedure, would be inappropriate. Therefore, we believe that 19290 and 19291 should remain on the ASC list for 2007.

* * *

Thank you for your consideration of our comments. FASA looks forward to continuing its work with CMS on the design and implementation of the revised ASC payment system so as to ensure that Medicare beneficiaries will have full access to the many benefits ASCs offer.

Sincerely,

Kathy J. Bryant
President

Enclosures: Exhibit A – FASA Comments on Procedures Predominantly Performed in Physician Offices for Addition to the ASC List for 2007

Exhibit B – FASA Comments on Other Procedures for Addition to the ASC List for 2007

Exhibit A

FASA Comments on Procedures Predominantly Performed in Physician Offices for Addition to the ASC List for 2007

CPT	Description	FASA Comments
11603	Excision of malignant skin lesion; excised diameter 2.1 to 3.0 cm	FASA believes that the same considerations which merit performance and coverage of 11604 (excised diameter 3.1 to 4.0 cm) apply to the excision of any malignant lesions larger that 2 cm. Privately-insured patients regularly obtain this procedure in ASCs.
28124	Partial removal of toe	CMS proposed to add this procedure to the ASC list in 1998. However, when the final rule was issued in 2003, the procedure was not added, nor was it added in 2005. As of yet, no explanation has been provided in the accompanying comments. The procedures relating to this code are all on the ASC list, including 28120, 28122 and 28126. Like these procedures, 28124 meets the criteria for being on the ASC list and the Medicare program and its beneficiaries could save money with its inclusion on the ASC list.
40812	Excise mouth lesion with simple repair	While this procedure is frequently performed in physician offices, when patients have multiple lesions or when a frozen section is needed to test for malignancy, a facility setting is needed.
45330	Diagnostic sigmoidoscopy	This is an example of a procedure that is commonly performed in physician offices, but where there are clear clinical justifications for performing it in an ASC for certain patients. Specifically, patients with gastrointestinal abnormalities (such as previous colon cancer or hemorrhoids) or other comorbidities (such as diabetes, heart disease or respiratory illness) are best served when anesthesia can be safely administered, the patient can be closely monitored and emergency response capability is readily available. As a result, these procedures often are performed in hospitals, at greater cost to the Medicare program and beneficiary, and should be on the ASC list.

62367 62368	Electronic analysis of programmable, implanted pump	This procedure was deleted from the ASC list in 2003, but merits special reconsideration because it is performed in conjunction with implantation of a infusion pump for spinal drug therapy, which is an ASC list procedure. According to the device manufacturers, it is necessary to analyze and program these pumps to assure that they are functioning properly and that the drug is being delivered appropriately. If this procedure is not on the ASC list, beneficiaries may need to visit a physician office following the procedure to have this programming performed. Several problems result from separating the programming from the implantation. For example, beneficiaries may have a non-functioning pump and thus may not be getting the desired pain relief until the follow-up physician appointment. With CMS's emphasis on appropriate pain management for the elderly, the agency should see this as a significant problem for Medicare beneficiaries. A similar issue is present when the pump is used for treating severe spasticity. The second visit, and we would argue unnecessary one, imposes additional expense and inconvenience for beneficiaries. This might not be a major issue for all beneficiaries, but for those in rural areas or with mobility problems, this additional, unnecessary visit could be a significant imposition. Finally, the follow-up appointment might be with a physician who is not as experienced in the use of infusion pumps, since physicians most experienced with these devices sometimes practice only in the ASC setting. CPT codes 62367 and 68238 were billed by ASCs 6,800 times in 2001 prior to their elimination from the ASC list, so their exclusion from the list affects a significant number of beneficiaries.
64402 64405 64408 64412 64413 64418 64425 64435 64445 64505	Injection of anesthetic agent (nerve block) for various somatic nerves	These procedures are already being performed on a regular basis for non-Medicare patients in the ASC setting. CMS should make these procedures available to Medicare beneficiaries as they often are performed in conjunction with other pain management procedures. By denying Medicare coverage for these procedures, CMS creates an obstacle to their efficient performance with other procedures in ASCs.
64508	Injection of anesthetic agent (nerve block) for carotid sinus	This procedure is already being performed on a regular basis for non-Medicare patients in the ASC setting. CMS should make this procedure available to Medicare beneficiaries as it is often performed in conjunction with other pain management procedures.

64555	Implantation of peripheral nerve neurostimulator	This procedure is already being performed on a regular basis for non-Medicare patients in the ASC setting. CMS should make this procedure available to Medicare beneficiaries as it is often performed in conjunction with other pain management procedures.
64612	Chemodenervation of muscle(s) innervated by facial nerve (e.g., for blepharospasm or hemifacial spasm)	This procedure is already being performed on a regular basis for non-Medicare patients in the ASC setting. CMS should make this procedure available to Medicare beneficiaries as it is often performed in conjunction with other pain management procedures.
67110	Repair of retinal detachment	This procedure requires a dedicated operating room to control infection and patient monitoring to assure patient safety. The average operating room time is approximately 45 minutes, with an average recovery time of less than 60 minutes. This procedure does not involve extensive blood loss, or major or prolonged invasion of body cavities or major blood vessels. It is not generally emergent or life threatening in nature.

Exhibit B

FASA Comments on Other Procedures for Addition to the ASC List for 2007

CPT	Description	FASA Comments
13153	Complex repair of wound to eyelids, nose, ears and/or lips, each additional 5 cm or less	This code is used with 13152 when the repair is greater than 7.5 cm. By definition, complex repairs require time-consuming interventions such as scar revision, debridement, and extensive undermining. Work on the areas of the face described by this CPT code requires meticulous attention to detail for optimal outcomes, and a repair of this magnitude adds to the complexity of the procedure. Time in the operating room may be significantly extended by each additional 5 cm requiring this type of repair. All the other codes in this series, 13150-13152, are currently on the ASC list and assigned to payment group 3. Excluding more extensive repairs from the ASC setting is not consistent. Moreover, three other would repair add-on codes (13102, 13122 and 13133) were proposed for addition to the ASC list for 2007. Based its similarity to the other proposed additions, CPT code 13153 also should be added to the ASC list.
19295	Image guided placement of metallic localization clip during breast biopsy	This add-on procedure is performed in conjunction with breast biopsies performed using imaging guidance (19102 and 19103), which are on the ASC list. CPT code 19295 is separately reimbursed under OPPS and is proposed for coverage in ASCs in 2008. FASA sees no reason to further delay coverage for this procedure in ASCs.
21390 21406 21407	Open treatment of eye socket fracture	These procedures are similar to other fracture treatment procedures on the ASC list and, like these codes, meet the clinical criteria for inclusion. Operating room time is less than 90 minutes and patients can be released after two hours of recovery. Moreover, these procedures are proposed for ASC coverage in 2008. FASA sees no reason to further delay coverage for these procedures in ASCs.
29866 29867 29868	Knee arthroscopy with autograft implantation or meniscal transplantation	These knee arthroscopy procedures were added as CPT codes in 2005 and are clinically similar to the 29800-29888 series of codes, which are on the ASC list. FASA believes that these procedures meet the criteria for being on the ASC list and should be added. They typically require approximately 45 minutes of operating time and one hour of recovery time. Major blood vessels are not affected and most patients do not suffer significant blood loss.

31620	Endobronchial ultrasound during bronchoscopic diagnostic or therapeutic procedures	This add-on procedure is performed in conjunction with bronchoscopy procedures (31622-31625), which are on the ASC list. CPT code 31620 is separately reimbursed under OPPS and is proposed for coverage in ASCs in 2008. FASA sees no reason to further delay coverage for this procedure in ASCs.
35470 35471 35475	Transluminal balloon angioplasty	These procedures meet the current clinical criteria for addition to the ASC list. They involve peripheral vessels, are safe to perform in an outpatient setting, take approximately one hour and require a four-hour recovery period. The procedures are similar to, but less invasive than, 37205 and 37206, which CMS added to the ASC list in 2005. They also are similar to 35476, which is proposed for addition to the ASC list in 2007.
35490 35492 35493 35494	Transluminal peripheral artherectomy	These procedures meet the current clinical criteria for addition to the ASC list. They are safe to perform in an outpatient setting, take approximately one hour and require less than four hours of recovery.
36100 36140	Establish access to artery	These procedures are safe to perform in the ASC, taking approximately 30 minutes with a recovery period of two to four hours. They relate to the diagnostic work necessary to determine if a stent is required and are routinely performed in a variety of settings, including a non-OR settings such as a physician offices and treatment rooms. There does not appear to be a clinical basis or sound policy reason for covering the placement of stents, but not related diagnostic procedures such as these.
43257	Upper gastrointestinal endoscopy with delivery of thermal energy to lower esophageal muscles	This code describes technology to treat gastric reflux disease – a growing problem for Medicare beneficiaries – through an endoscopic approach. It is clinically similar to other upper endoscopy procedures and, thus, meets the criteria for being on the ASC list. It is proposed for ASC coverage in 2008, and FASA sees no reason to further delay coverage for this procedure in ASCs.

47562 47563 47564	Laparoscopic cholecystectomy	FASA has been recommending that laparoscopic cholecystectomies be added to the ASC list since 1995, and CMS's failure to include this procedure on the ASC list is particularly frustrating given that the first laparoscopic cholecystectomy was performed in an ASC in 1988. Technological advances in anesthesia and laparoscopes make it safe and appropriate to perform these procedures in outpatient settings, which CMS apparently acknowledges by proposing to make 47562 and 47563 eligible for ASC payment in 2008 under the revised payment system. However, we believe all three CPT codes meet the current clinical criteria to be on the ASC list for 2007. A FASA survey from 2004 of companies operating a total of 54 ASCs that perform laparoscopic cholecystectomies provides data to substantiate this claim. The 54 ASCs, which performed 3,207 laparoscopic cholecystectomies in 2003, had an average procedure time of 65 minutes. The survey also found that the procedure was safe, with a complication rate of 1.15% and a transfer rate of less than 1%. This shows that virtually no patients required an overnight stay following a laparoscopic cholecystectomy in an ASC. When it is necessary to convert to an open cholecystectomy, the conversion typically is made and completed at the ASC. This is done for patient convenience (that is, so the initiated procedure can be completed) and to avoid a second anesthesia event. Only after the conclusion of surgery is the patient transferred via ambulance to the hospital for recovery. There is nothing about the ambulance trip that is medically significant, and there is no reason to believe that hospital outpatient departments are in a better position to handle these complications than ASCs. We recognize that the ASC might not be the appropriate site for all Medicare beneficiaries, as many will require an overnight recovery stay. By not putting laparoscopic cholecystectomies on the ASC list, however, CMS is denying all Medicare beneficiaries access to ASCs for these procedures. The ultimate responsibility for choosing the appropriate site of service for a surgical procedure should be strictly between patients and their physicians employing appropriate pre-operative selection criteria.

61795	Stereotactic computer assisted volumetric (navigational) procedure	Computer assisted surgical navigation (CASN) is an adjunctive surgical process that integrates real-time imaging into the primary procedure to enhance its safety and effectiveness. More specifically, CASN allows a surgeon to discriminate patient anatomy precisely and to access anatomy that may be difficult to find or reach. By enabling precise trajectories and identifying the location of surgical instruments relative to patient anatomy, CASN substantially minimizes trauma and the risk of secondary damage to patients. Code 61795 is a separately reimbursable procedure for hospital outpatient departments, and FASA believes the quality of care benefits of this significant breakthrough technology should be equally and immediately available in ASCs.
62290 62291	Injection procedures for diskography	Despite several previous comments requesting the addition of these diskography procedures, CMS has declined because they are considered non-interventional support for radiologic studies. In ASCs, these procedures often are performed immediately prior to an interventional diskectomy procedure. Thus, although diagnostic in nature, they should be added to the list to support the safe and efficient performance of diskectomy procedures in the ASC setting. Moreover, a growing number of diagnostic procedures are included on the ASC list. These include diagnostic injection procedures such as bronchography (CPT code 31656), cervical puncture with injection of diagnostic substances (61055), spinal injections of diagnostic substances (62310-62319) and diagnostic nerve blocks (64470-64483). Given the clear similarities between diskography and these other covered diagnostic injection procedures, we believe codes 62290 and 62291 should be added to the ASC list.
63030 63035 63042 63047	Low back disk surgery	While Medicare patients primarily have lower back disc surgery performed on an inpatient basis, a growing number of non-Medicare patients (and some Medicare patients who choose to pay out of pocket) are having these procedures performed in ASCs, often using endoscopically-assisted approaches. The procedures appear to meet the Medicare criteria for being on the ASC list. They are non-emergent, do not involve a major or prolonged invasion of a body cavity and do not involve major blood loss. In ASC settings, these procedures involve 60 to 90 minutes of operating room time and about 60 minutes of recovery time.

63655	Laminectomy for implantation of neurostimulator electrodes	This procedure is already being performed on a regular basis for non-Medicare patients in the ASC setting. CMS should make this procedure available to Medicare beneficiaries as it is often performed in conjunction with other pain management procedures. It is proposed for ASC coverage in 2008, and FASA sees no reason to further delay coverage for this procedure in ASCs.
64448 64449	Injection of anesthetic agent (nerve block) for femoral nerve or lumbar plexus, with continuous infusion by catheter	These procedures are already being performed on a regular basis for non-Medicare patients in the ASC setting. CMS should make these procedures available to Medicare beneficiaries as they often are performed in conjunction with other pain management procedures. By denying Medicare coverage for these procedures, CMS creates an obstacle to their efficient performance with other procedures in ASCs.
G2089	Arthroscopy, knee, surgical, for removal of loose body, foreign body	This is a special code created by CMS to address situations when, during a knee arthroscopy (29874 or 29877), at least 15 additional minutes of work is required in a compartment of the knee other than the one in which the primary procedure is being performed. In creating this code, CMS recognized that additional work was required, and CMS is paying physicians for the additional work involved. Thus, FASA believes that this code should be added to the ASC list so that ASCs also are reimbursed for the additional operating room time, which by definition is at least 15 minutes more, and for the supplies involved in this add-on procedure.