CMS-1429-FC-021

December 13, 2004

Response to CMS November 2004 ruling regarding changes to CPT code 88180 for flow cytometry
Dear CMS Officials,

This message is to express my serious concern regarding the drastic decrease in reimbursement for professional flow cytometry services proposed by CMS for 2005. The flow cytometric analysis of hematologic malignancies is a laborious procedure that combines sophisticated laboratory analysis with a significant component of physician work. As a physician with specialty training in hematopathology, I spend considerable time making decisions on sample handling and selection of reagents appropriate to the clinical context of indicvidual patients; examine complex graphical data; correlate results with microscopic observations; and generate meaningful interpretations that are often discussed directly, and always transmitted in writing to treating physicians. This information is critically important for making an accurate diagnosis of certain types of malignancies and is also vital for making appropriate treatment decisions.

I am aware of the process used to establish the new compensation proposed for this complicated activity under the 2005 CMS rules. However, I believe the process was flawed because those involved in evaluating this were forced to compare the proposed compensation to inappropriate reference codes. As a result, I firmly believe that the final assigned value for compensation is not reasonable.

Flow cytometry has been growing at a very rapid pace and has been responsible for major advances in the diagnosis, prognosis and treatment of patients with serious and life threatening diseases, including virtually all bone marrow and lymphoid cancers. As in all other developed countries, no patient with leukemia in the US is treated and monitored without the diagnostic support provided by flow cytometry. With flow cytometry, many patients who once needed surgical procedures to excise large amounts of tissue can now have diagnoses rendered on small biopsies from non-invasive, and far less expensive procedures. The radical cuts in reimbursement for flow cytometric services will result in decreased availability of this essential diagnostic modality. Numerous academic, independent and hospital-based laboratories currently involved in diagnostic flow cytometry are considering discontinuing these activities in 2005 and those that carry on will be forced to reduce the quality of their services in ways not necessarily apparent to the oncologists who are dependent on them.

I urge the CMS to begin a dialogue with those affected by the reimbursement cuts, by working with the College of American Pathologists and the Clinical Cytometry Society. Please consider reevaluating the proposed fee schedules to avoid the inevitable adverse impact these cuts will have on vulnerable patients who are dealing with life-threatening illnesses.

Sincerely,

Christopher D. McKinney, M.D.
Wilmington Pathology Associates
New Hanover Regional Medical Center
Department of Pathology and Laboratory Medicine

December 13, 2004
Response to CMS November 2004 ruling regarding changes to CPT code 88180 for flow cytometry
Re.: **CMS-1429-FC**

Dear CMS Officials,

This message is to express my serious concern regarding the drastic decrease in reimbursement for professional flow cytometry services proposed by CMS for 2005. The flow cytometric analysis of hematologic malignancies is a laborious procedure that combines sophisticated laboratory analysis with a significant component of physician work. As a physician with specialty training in hematopathology, I spend considerable time making decisions on sample handling and selection of reagents appropriate to the clinical context of indicvidual patients; examine complex graphical data; correlate results with microscopic observations; and generate meaningful interpretations that are often discussed directly, and always transmitted in writing to treating physicians. This information is critically important for making an accurate diagnosis of certain types of malignancies and is also vital for making appropriate treatment decisions.

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necessarily apparent to the oncologists who are dependent on them.

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Sincerely,

Christopher D. McKinney, M.D.
Wilmington Pathology Associates
New Hanover Regional Medical Center
Department of Pathology and Laboratory Medicine
2131 South 17th Street
Wilmington, NC 28401

CMS-1429-FC-22

Submitter: Dr. Preston Simpson
Date & Time: 12/14/2004
Organization: Dr. Preston Simpson
Category: Physician
Issue Areas/Comments GENERAL
See attachment

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

CMS-1429-FC-023

December 11, 2004
Response to CMS November 2004 ruling regarding changes to CPT code 88180 for flow cytometry

Dear CMS:

I am writing in an effort to prevent an impending crisis for patients with diseases of the blood, bone marrow, and lymph nodes, which will likely result from the recent drastic devaluation by CMS for both technical and professional component reimbursements for flow cytometry. As the Director of the Flow Cytometry Laboratory at Hartford Hospital (which serves not only the patients and doctors of Hartford Hospital and Connecticut Children's Medical Center, but also those of MidState Medical Center, New Britain General Hospital, Charlotte-Hungerford Hospital, and Middlesex Hospital), I am alarmed that these draconian cuts will precipitate the demise of a diagnostic test which has become the standard of care for patients who have, or are suspected of having leukemia, lymphoma, myeloma, or myelodysplasia. Effective January 1, 2005, CMS will reduce the technical reimbursement for flow cytometry to laboratories by approximately 40%. I have discussed this situation with our Laboratory Manager, and she has indicated that the proposed reimbursement will be insufficient to staff the laboratory with the Medical Technologists who perform the testing, let alone the costs of purchasing the necessary monoclonal antibody reagents. Thus, the hospital will likely be forced to send the patients' samples out of state to a very large reference lab. This will result in delays in the diagnosis of these life-threatening diseases. Even if the technical cuts were to be restored, there would remain the problem of professional reimbursement, which is slated to be reduced by approximately 70% for a standard leukemia evaluation. Once again, the proposed reimbursement will be insufficient to staff an adequate number of highly trained specialists in hematopathology, who must analyze the data, and formulate a diagnosis, which is the basis for the individual patient's treatment regimen. Having seen patients with leukemia die within 12 hours of arriving in the emergency room, prior to the institution of treatment, I am distraught to imagine
that would tolerate the inevitable delays in diagnosis which will result from the decreased local availability of flow cytometry.

In addition to the delays in diagnosis which will result from the reduced local availability of flow cytometry, patient care will suffer in other ways as well. For example, before the availability of flow cytometry as a diagnostic test, patients with enlarged lymph nodes in deep-seated anatomic locations were subjected to thoracotomy or laparotomy, in order to permit biopsy of the diseased nodes. With flow cytometry, however, hematopathologists need very few cells to render a specific diagnosis; as a result, these patients now routinely undergo CT-scan-guided fine needle aspiration and/or needle core biopsy, obviating the requirement for surgery. If flow cytometry is not locally available, we will likely see a return to the more invasive surgical procedures of the past in such patients. I wonder whether it is appropriate for CMS to force a senior with a mediastinal mass obstructing her airway to undergo thoracotomy, and spend days in the hospital recovering, because there is insufficient time to await the reeturn of results from a distant flow cytometry laboratory? I also wonder whether the cost to CMS of

surgery plus a several-day hospital stay for that senior will actually exceed the savings produced by the cuts to flow cytometry? I do not know how CMS determined that technical reimbursement for flow cytometry should be cut by 40%. However, I do know that the methodology by which professional reimbursement for flow cytometry was cut was fatally flawed by the lack of inclusion of comparable CPT codes. Pathologists completing the survey were forced to perform an “apples and oranges” comparison of the time and effort required for interpretation of flow cytometric testing with one of several procedures which were in no way similar to flow cytometry. For example, had the CPT code for interpretation of an immunofluorescence assay (which uses the same fluorochrome-labeled monoclonal antibodies that are used in flow cytometry) been included in the survey, the RVU for flow cytometry would actually have increased, not decreased.

In summary, I am afraid that CMS does not fully understand the ramifications of these proposed cuts for the care of patients with leukemia, lymphoma, and related disorders. In addition to reducing the quality of care for these patients, the cuts will likely have the ironic effect of increasing the overall cost to CMS of establishing a diagnosis in these patients. For these reasons, I am requesting a moratorium on the proposed changes in reimbursement to flow cytometry, in order to allow sufficient time adequately, and thoughtfully to consider alternative solutions. I would be more than happy to offer my expertise in this process. Thank you very much for your consideration.

Respectfully,

Joseph A. DiGiuseppe, M.D., Ph.D.
Director, Flow Cytometry Laboratory
Department of Pathology
Hartford Hospital
80 Seymour Street
Hartford, CT 06102-5037
Phone: (860) 545-4150
Fax: (860) 545-2204
e-mail: jdigius@harthosp.org

CMS-1429-FC-24

Submitter: Dr. Kenneth Rock
Date & Time: 12/15/2004
Organization: UMass Medical School
Category: Physician
Issue Areas/Comments GENERAL

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

I am writing to urge a reconsideration in the reduction in reimbursement for professional flow cytometry services proposed by CMS for 2005. This is a critical test for the diagnosis and evaluation of blood cancers. It is sophisticated, and time consuming. Hematopathologists direct the handling of the samples and make decisions on the work up of the case. The data that is acquired needs to be graphed, evaluated and may require reprocessing. These results then need to be correlated with histopathological analyses and clinical history. Reports are then written and results are often discussed at length with the patient's physicians to decide the course of treatment. I believe the process used to establish the new compensation schedule was flawed because it used inappropriate reference codes as comparators. As a result, I believe that the final assigned values for compensation is not reasonable. Patients and clinical care has greatly benefited from the advent of flow cytometry. This has obviated the needs in many patients for invasive surgery and gives much more accurate diagnosis. I believe that the drastic cuts in reimbursement for these services will result in decreased availability of this essential diagnostic modality. Numerous academic, independent and hospital-based laboratories are considering discontinuing these activities in 2005. Those that carry on will be forced to reduce the quality of their services in ways not necessarily apparent to the oncologists who are dependent on them. This will ultimately negatively affect patients and could may lead to an undesired and inadvertent outcome: decreased quality of care. I urge the CMS to delay implementation of these scheduled reductions, and to engage in a dialogue with those affected by the reimbursement cuts, so as to reevaluate the proposed fee schedules and prevent an adverse impact on patients.

CMS-1429-FC-25

December 17, 2004
Response to CMS November 2004 ruling regarding changes to CPT code 88180 for flow cytometry

Dear CMS,

This message is to express my serious concern regarding the drastic decrease in reimbursement for professional flow cytometry services proposed by CMS for 2005. The flow cytometric analysis of hematologic malignancies is a laborious procedure that combines sophisticated laboratory analysis with a significant component of physician work. Physicians, generally hematopathologists, must spend considerable time to make decisions on sample handling and selection of reagents appropriate to a clinical context; examine complex graphical data; correlate results with microscopic observations; and generate meaningful interpretations that are often discussed, and always transmitted in writing to treating physicians. I am aware of the process used to establish the new compensation proposed for this complicated activity under the 2005 CMS rules. However, I am concerned that the process was flawed because the process was forced to compare to inappropriate reference codes. As a result, I believe that the final assigned value for compensation is not reasonable.

Flow cytometry has been growing at a very rapid pace and has been responsible for major advances in the diagnosis, prognosis and treatment of patients with serious and life threatening diseases, including virtually all bone marrow and lymphoid cancers. As in all other developed countries, no patient with leukemia in the US is treated and monitored without the diagnostic support provided by flow cytometry. With flow cytometry, many patients who once needed surgical procedures to excise large amounts of tissue can now have diagnoses rendered on small biopsies from non-invasive, and far less expensive procedures. The radical cuts in reimbursement for flow cytometric services will result in decreased availability of this essential diagnostic modality. Numerous academic, independent and hospital-based laboratories currently involved in diagnostic flow cytometry are considering discontinuing these activities in 2005 and those that carry on will be forced to reduce the quality of their services in ways not necessarily apparent to the oncologists who are dependent on them. As the medical director of a small flow cytometry laboratory in a small community hospital, this issue is extremely disturbing.

I urge the CMS to begin a dialogue with those affected by the reimbursement cuts to reevaluate the proposed fee schedules and prevent an adverse impact on patients.

Sincerely,

Christopher S. Bee, M.D.
Staff Pathologist and Medical Director, Flow Cytometry
McKee Medical Center
2000 Boise Avenue
Loveland, CO 80538

CMS-129-FC-026

December 17, 2004
The Honorable Mark McClellan, M.D.
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

Dear Doctor McClellan:

I am contacting you on behalf of the Cancer Research and Prevention Foundation concerning the final rule for "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005" that was published in the November 2, 2004, edition of the Federal Register. The Cancer Research and Prevention Foundation is a national, non-profit health foundation whose mission is the prevention and early detection of cancer through scientific research and education. The Foundation focuses its energies and resources on those cancers - including lung, breast, prostate, colorectal, cervical, skin, oral and testicular cancers - that can be prevented through lifestyle changes or detection and treatment in their early stages.

We are encouraged that the Centers for Medicare and Medicaid Services (CMS) has taken initial steps, through the recently announced "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005" to help ensure that cancer patients receive quality care. Particularly, both the proposed demonstration program to improve quality of care for cancer patients undergoing chemotherapy and also the proposal beginning in January 2005 to provide a $24 per prescription supply fee to pharmacies that distribute oral drugs such as anti-cancer, anti-emetics and immunosuppressive drugs.

However, we believe that there is one important oversight in the demonstration project. CRPF is concerned that oral anti-cancer therapies are not included in the demonstration, and the project is limited to IV administered and push chemotherapy drugs.

We urge CMS to provide clarity to the provider community that the demonstration program will equally cover oral anti-cancer products with infusion chemotherapy treatments so that pertinent quality of life data are gathered from all available treatment options. We believe this is particularly important as oral anti-cancer treatments may provide better quality of care to cancer patients. If CMS is genuinely interested in measuring quality of life data, these oral agents must be included, as they often offer clinical equivalency if not superiority to traditional therapies and provide overall cost-savings to the health system.

Further, without reimbursement for services included in the demonstration project, physicians may be less inclined to prescribe oral therapies even though they provide greater flexibility to patients than traditional chemotherapy treatments. Additionally, we remain concerned that beneficiaries' access to cancer therapies may still be limited. In particular, Medicare patients will be forced to pay a twenty

percent (20 percent) co-pay for being evaluated by a physician for quality of life issues in the demonstration project. Although these services will help to evaluate quality of life factors for patients, we are concerned that many patients may be unwilling or unable to assume this financial burden. It is our belief that Medicare patients should not be required to take on this added financial burden for services that have the potential to provide cost savings to CMS and the Medicare system.

Thank you for your consideration of our comments. We are encouraged by the steps CMS has taken to ensure Medicare beneficiaries have uninterrupted access to quality cancer care and appreciate CMS' continued work in this area. We hope that CMS will work to ensure that all Medicare beneficiaries continue to receive the highest quality cancer care available and that current and future regulatory decisions support breakthrough research and drug development that is critical to cancer care.

Sincerely,

Carolyn R. Aldigè
President and Founder

CMS-1429-FC-27

Submitter:
Date & Time: 12/21/2004
Organization : AARP
Category : Other Association
Issue Areas/Comments GENERAL

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

SEE ATTACHMENT CMS-1429-FC-27-Attach-1.DOC

Department of Health and Human Services
Centers for Medicare and Medicaid (CMS)
7500 Security Blvd
Baltimore, Maryland 21244

Below you will find a brief explanation why an attachment can not be provided at this time on a particular document at this time, which was as indicated by the commenter. If you wish to view those attachments that have not been posted, please call CMS at 410-786-9994 or 410-786-7195 Monday through Friday to schedule an appointment.

1. The commenter failed to complete all steps required in order to process their comments. All required fields must be completed in order to attach an attachment.

2. The commenter was referring to another comment received, but did not attach the information they were referring to.

3. The commenter intended to attach more then on attachment. But for some reason, CMS only received one or neither of their attachment.

4. The commenter provided sensitive information, that CMS felt was inappropriate to be posted on the web site.

CMS-1429-FC-28

Submitter: Dr. Ajit Alles
Date & Time: 12/21/2004
Organization: Cook Children's Medical Center
Category: Physician
Issue Areas/Comments GENERAL

December 21, 2004

I wish to express my dismay at the drastic decrease in reimbursement for professional flow cytometry services proposed by CMS for 2005. The flow cytometric analysis of neoplasms is a laborious procedure that combines sophisticated laboratory analysis with a significant component of physician work. Physicians spend a considerable amount of time making decisions on sample handling and selection of reagents appropriate to a clinical context, examining complex graphical data, correlating results with microscopic observations and generating meaningful interpretations. Flow cytometry has been growing at a very rapid pace and has been responsible for major advances in the diagnosis, prognosis and treatment of patients with serious and life threatening diseases, including virtually all bone marrow and lymphoid cancers. As in all other developed countries, no patient with leukemia in the U.S. is treated or monitored without the diagnostic support provided by flow cytometry. Indeed, all current classifications of hematolymphoid neoplasms require flow cytometry to appropriately classify these entities. With flow cytometry, many patients who once needed expensive surgical procedures to excise large amounts of tissue can now have diagnoses rendered on small biopsies from minimally invasive, cost effective procedures. The radical cuts in reimbursement for flow cytometric services will result in decreased availability of this essential diagnostic modality. I am aware of the process used to establish the new compensation proposed for this complex activity under the 2005 CMS rules, but the process was flawed because inappropriate reference codes were used for comparison. As a result the final assigned value for compensation is not reasonable and will lead to a reduction in diagnostic services. Numerous academic, independent and hospital-based laboratories currently involved in diagnostic flow cytometry are considering discontinuing these activities in 2005, directly as a result of these reimbursement changes. Laboratories that do continue to offer flow cytometry will be forced to reduce the quality of their services, possibly leading to inappropriate diagnosis and treatment. I urge the CMS to reopen a dialogue with those affected by the reimbursement cuts to reevaluate the proposed fee schedules and prevent an adverse impact on patients.
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Sincerely,

Ajit J. Alles, MD, PhD
Department of Pathology and Laboratory Medicine
Cook Children?s Medical Center

CMS-1429-FC-29

Submitter: Ms. Carol Kelly
Date & Time: 12/21/2004
Organization: Advanced Medical Technology Association
Category: Device Association
Issue Areas/Comments GENERAL

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

See Attachment Issues Interim Work Relative Value Units AdvaMed is concerned that the interim relative values assigned to the new CPT codes for flow cytometry testing (88184, 88185, 88187, 88188, and 88189) represent a significant reduction in reimbursement for these tests from current year rates. See Attachment.CMS-1429-FC-29-Attach-1.DOC CMS-1429-FC-29-Attach-1.DOC

December 21, 2004

Mark McClellan, MD, Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1429–FC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Comments on Interim Values for Selected New CPT Codes Describing Flow Cytometry Procedures [CMS-1429-FC]

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to comment on interim values for selected new CPT codes describing flow cytometry procedures (88184, 88185, 88187, 88188, and 88189) as published in the final rulemaking governing the Physician Fee Schedule for calendar year 2005, published in the Federal Register on November 15, 2004.

AdvaMed is the largest medical technology trade association in the world, representing more than 1,100 innovators and manufacturers of medical devices, diagnostics, and health information systems—innovative products which diagnose, treat, sustain and improve the quality of life for Medicare beneficiaries.

AdvaMed is concerned that the interim relative values assigned to the new CPT codes for flow cytometry testing (88184, 88185, 88187, 88188, and 88189) represent a significant reduction in reimbursement for these tests from current year rates. We understand CMS's concerns related to the ways providers have traditionally ordered and billed for flow cytometry procedures under deleted code 88180, as the agency has publicly communicated its position in previous rulemaking (CMS-1476-P and CMS-1476-FC). However, we have several significant concerns with respect to the process and data utilized for assigning what appears to be an improper valuation for at least one of the new codes (88185).

Specifically, we are concerned about the following issues:

Clinical Impact: We are extremely concerned about reports from clinicians and others that the significant cuts, particularly in testing for leukemia and lymphoma, will lead to a reduction in this important testing. The newer codes seem to be based on an average calculation of fewer markers, yet experts in the field indicate that testing of fifteen to twenty markers represents the standard of care for leukemias and lymphomas..

Process Issues: The fact that value for the technical component code (88185) is first being

communicated in a final rule is very troublesome for this level of a cut – more than 50% for the typical leukemia or lymphoma case. Since this value was not available in the proposed rules, there was no opportunity for stakeholders to provide constructive comment for consideration and possible revaluation. We believe that the reductions will create a hardship for many laboratories and subsequently for the patients they serve.

Data Concerns: We believe that the value for code 88185 does not accurately reflect the full costs and labor involved with the technical components of flow cytometry. While some economies of scale may exist when multiple markers are tested for the same patient in a single episode, we do not believe that the data would support a fifty percent cut in the technical rate for all subsequent markers.

Given these concerns, we request the opportunity to meet and discuss these issues with the agency as soon as possible. In the meantime, we respectfully request that these changes to the technical component reimbursement for flow cytometry testing not be implemented until the value can be reevaluated.

We look forward to working with you to address this important issue.

Sincerely,
/s/
Carol Kelly
Executive Vice President
Direct: 202 434 7203
ckelly@AdvaMed.org
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

Bringing innovation to patient care worldwide

CMS-1429-FC-030

Administrator Mark McClellan, M.D. Ph.D. December 22, 2004
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator McClellan:

On behalf of The Academy of Molecular Imaging (AMI), the Society of Nuclear Medicine (SNM) , the American College of Radiology (ACR), and the American College of Nuclear Physicians (ACNP) we are writing to comment on coding for Positron Emission Tomography Scans (PET scans). We appreciate the continued efforts of CMS to work with members of the nuclear medicine and oncology community on billing and reimbursement issues relating to these studies. One issue we have raised over the past several years is the billing of PET scans and the appropriate coding. We would like to recommend that CMS move to the newly established CPT 2005 codes for PET and PET /CT (for anatomical localization) procedures. These codes would replace the existing G codes.

The PET G codes create difficulties for hospitals tracking and billing not only because of their number and complexity, but also for their primary use by Medicare. Most other patients are reported using the standard CPT coding system. Recently six new CPT codes were created for tumor imaging with PET and PET/CT. These will allow CMS to track utilization of PET scans and allow for proper and uniform billing of scans by hospitals and practitioners. Our organizations would be willing to work with you to implement billing and coding changes and to assist with provider education.
The change to CPT codes from G Codes should not affect reimbursement levels for these scans. The reimbursement levels under the CPT codes should be consistent with the present reimbursement rate under the G codes.

We would appreciate meeting with CMS to discuss this issue, including the role of PET with concurrent CT for anatomical localization. If you wish you may contact me directly at mckusick@capecod.net, 508) 255-8178 or Denise Merlino at dmerlino@snm.org, 781-435-1124.Thank you very much for your attention to this matter.

Sincerely,

Kenneth McKusick M.D. FACR FACNP
For the AMI, ACNP, ACR and SNM Inc.

CMS-1429-FC-31

Submitter: Dr. David Wilkinson
Date & Time: 12/22/2004
Organization: Virginia Commonwealth University
Category: Physician
Issue Areas/Comments GENERAL

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Response to CMS November 2004 ruling regarding changes to CPT code 88180 for flow cytometry This message is to express my deep concern and frustration regarding the drastic decreases in reimbursement for professional flow cytometry services proposed by CMS for 2005. These changes will heavily impact compensation for pathologists and laboratories and jeopardize continuation of flow cytometry services. Most importantly, these changes increase the likelihood of a reduced availability of flow cytometry to those who need it most ? patients with leukemias and lymphomas. This could mean delaying treatment of children and the elderly with this life-threatening form of cancer. I urge CMS to postpone implementation of these scheduled reductions, and to engage in a dialogue with those affected by the reimbursement cuts, so as to reevaluate the proposed fee schedules and prevent an adverse impact on patients. The flow cytometric analysis of hematologic malignancies is a laborious procedure that combines sophisticated laboratory analysis with a significant component of physician work. Physicians, generally highly trained hematopathologists, must spend considerable time to perform the following: ? On an immediate basis, make decisions on sample handling, and selection of reagents appropriate to a clinical context; ? Examine complex graphical data and reprocess data based on initial interpretation; ? Correlate results with microscopic observations and with complex clinical information; ? Generate meaningful interpretations that are always transmitted in writing to treating physicians; and ? Very often, discuss flow cytometry findings at length with the treating physicians. The pathology community is well aware of the process used to establish the new compensation proposed for this complicated activity under the 2005 CMS rules. However, we are concerned that the process was flawed because we were forced to compare to inappropriate reference codes. As a result, we believe that the final assigned values for compensation is not reasonable. Flow cytometry has been growing at a very rapid pace and has been responsible for major advances in the diagnosis, prognosis and treatment of patients with serious and life threatening diseases, including virtually all bone marrow and lymphoid cancers. As in all other developed countries, no patient with leukemia in the US is treated and monitored without the diagnostic support provided by flow cytometry. ? With flow cytometry, many patients who once needed surgical procedures to excise large amounts of tissue can now have comprehensive initial diagnoses rendered on small biopsies from non-invasive, less-disfiguring, and far less expensive procedures. This benefits both insurance carriers as well as the patients. ? Flow cytometry permits rapid yet comprehensive analysis of the status of patient?s leukemia or lymphoma during treatment, and hence enables better tracking of disease status and response to treatment. The radical cuts in reimbursement for flow cytometric services

CMS-1429-FC-32

December 22, 2004

Submitter Mary Duenzl
Date & Time: 12/22/2004
Organization: Clinical Cytometry Society
Category: Other Health Care Professional
Issue Areas/Comments GENERAL

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Response to CMS November 2004 ruling regarding changes to CPT code 88180 for flow cytometry Re.: CMS-1429-FC Dear CMS, This message is to express my serious concern regarding the drastic decrease in reimbursement for professional flow cytometry services proposed by CMS for 2005. The flow cytometric analysis of hematologic malignancies is a laborious procedure that combines sophisticated laboratory analysis with a significant component of physician work. Physicians must spend considerable time to make decisions on sample handling and selection of reagents appropriate to a clinical context; examine complex graphical data; correlate results with microscopic observations; and generate meaningful interpretations that are often discussed, and always transmitted in writing to treating physicians. We are aware of the process used to establish the new compensation proposed for this complicated activity under the 2005 CMS rules. However, we are concerned that the process was flawed because we were forced to compare to inappropriate reference codes. As a result, we believe that the final assigned value for compensation is not reasonable. Flow cytometry has been growing at a very rapid pace and has been responsible for major advances in the diagnosis, prognosis and treatment of patients with serious and life threatening diseases, including virtually all bone marrow and lymphoid cancers. As in all other developed countries, no patient with leukemia in the US is treated and monitored without the diagnostic support provided by flow cytometry. With flow cytometry, many patients who once needed surgical procedures to excise large amounts of tissue can now have diagnoses rendered on small biopsies from non- invasive, and far less expensive procedures. The radical cuts in reimbursement for flow cytometric services will result in decreased availability of this essential diagnostic modality. Numerous academic, independent and hospital-based laboratories currently involved in diagnostic flow cytometry are considering discontinuing these activities in 2005 and those that carry on will be forced to reduce the quality of their services in ways not necessarily apparent to the oncologists who are dependent on them. I urge the CMS to begin a dialogue with those affected by the reimbursement cuts to reevaluate the proposed fee schedules and prevent an adverse impact on patients.

Sincerely,

Mary L Duenzl, MT(ASCP)
Department of Pathology and Laboratory Medicine

CMS-1429-FC-32

December 22, 2004

Submitter Mary Duenzl
Date & Time: 12/22/2004
Organization: Clinical Cytometry Society
Category: Other Health Care Professional
Issue Areas/Comments GENERAL

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Response to CMS November 2004 ruling regarding changes to CPT code 88180 for flow cytometry Re.: CMS-1429-FC Dear CMS, This message is to express my serious concern regarding the drastic decrease in reimbursement for professional flow cytometry services proposed by CMS for 2005. The flow cytometric analysis of hematologic malignancies is a laborious procedure that combines sophisticated laboratory analysis with a significant component of physician work. Physicians must spend considerable time to make decisions on sample handling and selection of reagents appropriate to a clinical context; examine complex graphical data; correlate results with microscopic observations; and generate meaningful interpretations that are often discussed, and always transmitted in writing to treating physicians. We are aware of the process used to establish the new compensation proposed for this complicated activity under the 2005 CMS rules. However, we are concerned that the process was flawed because we were forced to compare to inappropriate reference codes. As a result, we believe that the final assigned value for compensation is not reasonable. Flow cytometry has been growing at a very rapid pace and has been responsible for major advances in the diagnosis, prognosis and treatment of patients with serious and life threatening diseases, including virtually all bone marrow and lymphoid cancers. As in all other developed countries, no patient with leukemia in the US is treated and monitored without the diagnostic support provided by flow cytometry. With flow cytometry, many patients who once needed surgical procedures to excise large amounts of tissue can now have diagnoses rendered on small biopsies from non- invasive, and far less expensive procedures. The radical cuts in reimbursement for flow cytometric services will result in decreased availability of this essential diagnostic modality. Numerous academic, independent and hospital-based laboratories currently involved in diagnostic flow cytometry are considering discontinuing these activities in 2005 and those that carry on will be forced to reduce the quality of their services in ways not necessarily apparent to the oncologists who are dependent on them. I urge the CMS to begin a dialogue with those affected by the reimbursement cuts to reevaluate the proposed fee schedules and prevent an adverse impact on patients.

Sincerely,

Mary L Duenzl, MT(ASCP)
Department of Pathology and Laboratory Medicine

CMS-1429-FC-033

December 22, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Baltimore, MD 21244-8012

Dear Dr. McClellan,

The American Academy of Neurology would like to respond to the final rule "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005," as published in the Federal Register on November 15, 2004.

Five-Year Refinement of Relative Value Units
The AAN appreciates the opportunity to identify codes that we believe are misvalued.

24-hour EEG
We request CPT code 95953: Monitoring for localization of cerebral seizure focus by computerized portable 16 or more channel EEG, electroencephalographic (EEG) recording and interpretation, each 24 hours be revalued. The current RVU is 3.08. We believe the time, intensity, and complexity of the physician work involved in this code justifies a higher work RVU.

Thank you for your consideration of our request.

Sincerely,
Laura Powers, MD
Chair, AAN Medical Economics and Management Committee

CMS-1429-FC-34

December 23, 2004

Submitter: Dr. Timothy Griffin
Date & Time: 12/23/2004
Organization: Cook Children's Physician Network
Category : Physician
Issue Areas/Comments Issues Interim Work Relative Value Units

Subject: November 2004 Medicare ruling for flow Cytometry CPT codes CMS-1429-FC To Whom It May Concern: I am writing this email to you to express my grave concern over the severe decreases in reimbursement for flow cytometry services proposed by CMS. As an oncologist treating patients with malignancies, I require the services of an excellent flow cytometrist/ hematopathologist in order to adequately diagnose and treat these patients. Many of the major advances in the success of treating patients with leukemia and lymphoma over the last twenty years have been predicated on this diagnostic modality. If a cut in reimbursement were to result in decreased availability of flow cytometry services, our patients would be severely adversely impacted. This should not be allowed to happen. This is a crucial diagnostic/prognostic pathology service. I urge CMS to withhold these drastic cuts in reimbursement and allow the medical community to present information for a more appropriate billing and reimbursement structure. Sincerely, Timothy C. Griffin M.D. 901 Seventh Ave. Ste. 220 Fort Worth, TX 76104

CMS-1429-FC-35

Submitter: Date & Time: 12/23/2004
Organization: American Academy of Family Physicians
Category: Health Care Professional or Association
Issue Areas/Comments GENERAL

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

See Attachment CMS-1429-FC-35-Attach-1.DOC

December 16, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing on behalf of the American Academy of Family Physicians, which represents more than 93,700 family physicians and medical students nationwide. Specifically, I am writing to offer our comments on the final rule with comment period regarding "Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005," as published in the Federal Register on November 15, 2004.

Publishing Relative Value Units (RVUs) for Noncovered Services

The final rule notes that CMS received requests from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) and the American Academy of Pediatrics to publish RVUs for noncovered services for which the RUC has made recommendations. In response, CMS states, "Because we have not yet established a consistent policy regarding the publication of RVUs for noncovered services, we will need to examine this issue further to carefully weigh the pros and cons of publishing these RVUs for noncovered services."

We strongly urge CMS to publish RVUs for noncovered services. The RVUs in the Medicare fee schedule are used extensively in the private sector, where coverage differs from Medicare. Publication of the RVUs for noncovered Medicare services would facilitate payment of those services in a resource-based manner by other payers. As CMS notes in the final rule, it has published RVUs for some noncovered codes (e.g., preventive medicine visits), and we have observed no "cons" as a result. We believe that CMS must take full responsibility for the resource-based relative value scale that it administers and publish RVUs for all services on the scale, whether they are covered by Medicare or not.

Medicare Modernization Act (MMA) Section 611 – Preventive Physical Examination

In the final rule, CMS made several revisions to the regulations regarding the new initial preventive physical examination (also known as the Welcome to Medicare Visit (WMV)) in response to comments

made by the Academy and others. For instance, as we suggested, CMS revised 42 CFR 410.16(a) (1) (i), as it relates to service element 1, to read, "Review of the individual's medical and social history with particular attention to modifiable risk factors for disease." Other changes that CMS made consistent with our comments include:

* Revising the definition of "social history" to eliminate less relevant elements (e.g., work, travel history, and social activities) in favor of more critical elements such as diet, physical activities, and history of alcohol, tobacco, and drug use.
* Revising and clarifying the regulation as it relates to depression screening and screening for functional ability and level of safety
* Revising and clarifying the regulations surrounding a "written plan" to indicate that this implies a brief written plan such as a checklist

In short, it appears that CMS addressed most, if not all, of our concerns related to the content of the WMV.

We wish we could say the same with respect to the corresponding payment policy. Instead, CMS will proceed to implement a new G code (G0344) for this service and assign RVUs corresponding to a 99203. Nor does the final rule fully address questions surrounding provision of a screening electrocardiogram (EKG) in conjunction with the WMV. It only reiterates that the WMV must include an EKG, either provided by the entity doing the WMV or by an outside entity under arrangement with the entity doing the WMV, and states, "Billing instructions . . . will be issued."

CMS did commit to "looking at the data and consulting with the medical community after initial experience with this new benefit to determine if this payment has been valued appropriately." It also agreed to remove the proposed restriction limiting the level of a problem-oriented E/M service done in conjunction with a WMV. For this, we offer our tepid thanks.

Health Professional Shortage Area (HPSA) Zip Code Areas

We were likewise disappointed in CMS's response to our comments on its proposals to implement MMA section 413, regarding HPSAs and Physician Scarcity Areas (PSAs). In particular, we believe that CMS misunderstood or misconstrued our comments about CMS's proposal that the only physicians eligible to receive the 10 percent incentive payment in mental health HPSAs that do not overlap with primary care HPSAs are psychiatrists. We argued that that all physicians providing mental health services in a mental health HPSA should be eligible for the bonus, since the proposal otherwise implies that only psychiatrists furnish mental health services and thus only psychiatrists should be eligible for the HPSA bonus in mental health HPSAs.

In response to our comment, CMS stated in the final rule:

However, in the situation where the mental health HPSA does not overlap with a primary medical care HPSA, we allow only psychiatrists to collect the incentive payment. Within these standalone mental

health HPSAs, there is an adequate supply of physicians for the provision of medical services and a shortage only of those providing mental health services. Therefore, it would be inconsistent with the HPSA incentive payment provisions, as well as an inappropriate use of the Medicare Trust Fund, to pay bonuses to physicians who furnish medical services in service areas without shortages of primary medical services.

CMS cannot seem to grasp the fact that family physicians and other physicians who furnish medical services also furnish mental health services. When a family physician in a mental health HPSA provides mental health services, we believe that he or she should be entitled to the HPSA bonus just as a psychiatrist would.

As we stated in our comments on the proposed rule, we can find no statutory basis for this rule. Section 1833(m) of the Social Security Act, which governs the HPSA bonus, only refers to "physicians" and "physician services," as does section 42 USC 254e, which governs the designation of HPSAs. Neither one, by our reading, excludes physicians from the HPSA bonus based on physician specialty. Indeed, in 42 CFR 414.67(b), CMS makes the HPSA bonus in primary medical care HPSAs open to all physicians, not just primary care physicians. That means CMS would pay a bonus to a psychiatrist for providing medical care in a primary care HPSA but would refuse to pay a family physician for providing mental health care in a mental health HPSA. This is a double-standard and completely unjustified from our perspective.

We note that family physicians have traditionally focused on treating the whole patient, and recognize the mind, body and spirit connection. Promotion of mental health and diagnosis and treatment of mental illness in the individual and family context are integral components of family medicine. Indeed, family physicians are uniquely positioned to recognize and treat problems in the continuum from mental health to mental illness. Through residency training and continuing medical education, family physicians are prepared to manage mental health problems in children, adolescents, and adults of all ages. The continuity of care inherent in most family medicine settings makes early recognition of problems possible. Also, family physicians are able to treat those individuals who would not access traditional mental health services because of the perceived stigma of mental illness. Appropriate consultation and referral to other specialties is a part of family medicine in regard to mental health/illness as it is in all other areas of patient care.

For all of these reasons, we again urge CMS to either not implement proposed 42 CFR 414.67 or otherwise revise it so that all physicians providing mental health services in a mental health HPSA are eligible for the bonus as it relates to mental health services.

Drug Administration Payment Policy

In reviewing the final rule as it relates to drug administration payment policy, we noted that CMS has finally addressed a longstanding inequity in physician payments as it relates to immunization administration. Specifically, CMS has historically not assigned any physician work to immunization administration. CMS reversed its position in the final rule, stating, "We agree with the commenter that

the physician work and practice expenses associated with administering injections are similar to immunizations." Accordingly, CMS will now assign the physician work value recommended by the RUC for vaccine administration and diagnostic/therapeutic injections. We strongly applaud CMS for this change in payment policy.

In the same section of the final rule, we were struck by the description of the demonstration project in which CMS proposes to pay $130 per encounter to physicians who take care of and administer chemotherapy to oncology patients for reporting a set of three new G codes that reflect patient-reported assessments of pain, fatigue, and nausea/vomiting. According to the final rule, the information gleaned will help CMS work with those who care for cancer patients to determine ways to improve the quality of care and quality of life for patients.

We may be missing something, but $130, which is more than CMS plans to pay for a 99215 in 2005, seems to be an extraordinary incentive to report chemotherapy patients' self-perceptions about their pain, fatigue, and vomiting/nausea. We imagine that many family physicians would be more than happy to report any number of patient-reported perceptions for an extra $130 per encounter, and we suspect there are better ways to make use of these Trust Fund dollars. We encourage CMS to re-think this demonstration project or at least the bounty it's paying for requested data.

Outpatient Therapy Services Performed "Incident to" Physicians' Services

We appreciate CMS's consideration of our comments as they related to its proposal to require persons providing outpatient therapy (i.e., physical therapy, occupational therapy, or speech-language pathology) to meet the standards in 42 CFR 484.4 (except licensure) in order for their services to be billed as incident to a physician's services. We also appreciate CMS's modification to reflect that in states that authorize physicians, physician assistants, nurse practitioners, and clinical nurse specialists to provide one or more of the therapy services, those non-physician providers may provide the services incident to the services of a physician under the same conditions as physicians (i.e., without meeting the training requirements applicable to therapists). This modification should ease the burden of this regulatory change for many family physicians. For other family physicians, CMS's decision to delay implementation until manual instructions are published (i.e., on or after March 1, 2005) will provide time to make alternative arrangements in their practices. We remain concerned that CMS's decision will still adversely affect access to such services in rural and other areas of the country.

Interim RVUs in Addendum C

CMS invited comments on the interim RVUs published in Addendum C of the Final Rule. We would like to offer comments on the following codes:

G0351 (Therapeutic/diagnostic injection) and 90471 and 90472 (Immunization administration)

As indicated above, we fully support CMS's decision to implement the RUC recommended work RVUs for these codes. We believe these services are more appropriately valued as a result.

G0344 (Initial preventive exam)

We continue to believe this service is undervalued by equating it to a 99203. The payment allowance for this service (unadjusted geographically) will be $97.02 in 2005.

As we stated in our comments on the proposed rule, we believe this service, as described in both the statute and the proposed regulations, is more consistent with the current CPT codes for preventive medicine services. Assuming this to be a new patient, as CMS has done, and assuming the typical Medicare beneficiary is eligible based on age (i.e., 65 years or older), the corresponding CPT code is 99387. Currently, Medicare assigns a total of 4.00 RVUs to this non-covered service in the office setting, as compared to 2.57 for G0344. We strongly encourage CMS to fulfill its commitment to consult with the medical community (i.e., the RUC) to determine if this new benefit has been valued appropriately.

Five Year Refinement of Work Relative Value Units for Calendar Year 2004

We request that CMS review the work relative value units (RVUs) of the following evaluation and management (E/M) services during the Five-Year Review of the Medicare Fee Schedule:

99201-99205	Office visits, new patient
99211-99215	Office visits, established patient
99221-99223	Initial hospital care
99231-99233	Subsequent hospital care
99238-99239	Hospital discharge services

We believe that the work of these services has changed significantly since these codes were reviewed during the first five-year review. As a result, we believe that they are undervalued relative to other services in the Medicare physician fee schedule.

Why We Believe the Work of E/M Services Has Changed in the Last Ten Years

I. Medical Practice Has Changed.

Comparing circumstances now to circumstances ten years ago, when the E/M codes were last subject to review, medical practice has changed considerably. It has changed even more in the fifteen or more years since the original Harvard work, which still appears to serve as the basis of physician time for these codes. Changes include:

1. A greater expectation that physicians will be proactive in diagnosing and treating illness

There is a greater expectation on the part of both patients and payers that physicians will be proactive in disease prevention, health promotion and the early diagnosis and treatment of disease. This expectation

is evidenced by the increasing number of screening services covered under the Medicare program. In the last ten years, Congress has added the following benefits to the Medicare program:

* Screening mammograms
* Screening Pap smears and pelvic exams (including a clinical breast exam)
* Colorectal cancer screening
* Prostate cancer screening
* Bone mass measurements
* Glaucoma screening

In 2005, Medicare will add diabetes screening, screening cardiovascular blood tests, and the "Welcome to Medicare" visit to this list. These benefits represent the application of proven technologies. Each has been demonstrated in published clinical trials or by expert panel consensus over the last 15 years to have a beneficial effect on the health of the population. However, they change the nature of medical practice from being reactive to being proactive. That change has implications for the physician work inherent in medical practice, such as the documentation and scheduling of routine tests, the motivation of patients to undergo tests such as mammograms that are uncomfortable and the follow up of results and patients who fail to make appointments for tests. It also has implications for both the intraservice intensity and pre- and post-service time involved.1

2. Additional documentation requirements added to physician work

The implementation of the 1995 and 1997 Medicare E/M documentation guidelines has increased documentation demands related to stand-alone E/M services. These guidelines did not exist the last time the E/M codes were reviewed. This adds to the physician work of E/M services relative to other services, which are not subject to the documentation guidelines. Even global surgical services, which include an E/M component, are unaffected by the advent of the documentation guidelines, since E/M services in the global period are not separately reported.

Medicare is not the only one requiring increased documentation. The Joint Commission on the Accreditation of Healthcare Organizations has also increased its documentation requirements as it relates to hospital visits.

The advent of electronic health records, while facilitating access to patient information, has created new work for clinicians. Medication and problem lists must be accurately maintained by providers. Furthermore, with the multiple medications now required by many patients, monitoring for drug-drug interactions becomes an essential component for quality care.

The impact of increased documentation requirements on intraservice work and pre- and post-service time cannot be overestimated. A survey of clinical oncologists, backed up by activity logs and site visits, revealed that more than 97% of survey respondents reported an increase in documentation (averaging 1.4 hours per day) and 77% reported an increase in work hours because of documentation in the previous five years.2

3. An increase in the complexity of data to be evaluated and care to be managed

Evaluation and management of patients involves integrating much more information than it did ten years ago, which increases the intraservice intensity of E/M services and add to the pre- and post-service time involved. As noted below, there are more informed consumers who want to and should be actively involved in decision-making, and they bring more information with them to their visits.

There is also more polypharmacy. For example, heart failure programs expect the concurrent management of 5-7 medications, and the JNC 7 hypertension recommendations3 support 2-4 medications for good control.

Further, there has been an explosion in the number of clinical guidelines that are good examples of what is considered optimal care. Add to this all of the new diagnostic and screening tests that have come into existence over the past ten years, with their corresponding results to be considered, and it is no wonder that the complexity of care of even the most common conditions (e.g., diabetes) has increased.4,5

We also note that the benefits of the successful co-management of the concurrent conditions of hypertension, diabetes, lipid abnormalities, and obesity have been demonstrated in clinical trials. Patients successfully treated in all areas had a 53% lower risk for cardiovascular disease.6 The application of the proven benefits of currently available therapies requires both intense and effective direct patient contact and expanded pre- and post-visit attention. The value of such continuous effective care needs to be recognized by appropriately valuing E/M services.

4. Patients presenting to the office with a greater expectation of participating in medical decision-making and with more information from the Internet and lay press.

There is a new paradigm of medical decision-making that has evolved over the last ten years. The doctor and patient are in a collaborative relationship, each with unique and important information components. Decisions are now “shared,” which is to say that the hierarchy of physicians instructing patient has been replaced by a more equal doctor patient discussion around diagnostic testing and treatment strategies.7,8

Additionally, ten years ago, the Internet and World Wide Web were a novelty accessed by few and used effectively by even fewer. Today, the Internet and World Wide Web are part of everyday life, accessed daily by millions of Americans. As with any technological advance, the growth of the Internet has both positive aspects (i.e., more information available more readily to more people) and negative aspects (i.e., more misinformation available more readily to more people). Patients today routinely present to the office with information that they have gleaned from the Internet and with questions about the veracity and applicability of that information in their circumstances.

As a result, counseling and coordination of care that physicians do within the context of E/M services requires more time and better preparation than ten years ago. Physicians must be more mindful of the

popular impressions and expectations, both good and bad, created by the mass media and developed on the Internet.

5. The advent of online communications with patients

Ten years ago, patients did not typically communicate with physicians by e-mail or other online means. They either called the office or came in for a visit. Today, e-mail is ubiquitous, and patients routinely communicate with physicians through this medium. Further, patients are interested in getting e-mail updates about new advances in treatment. Patients are also interested in virtual visits for simple and chronic medical problems and for following chronic conditions through virtual means.9,10 As growth and communication via the Internet continue, providers of E/M services must adapt to meet their patients' needs. CMS did not account for online communication with patients when the E/M codes were evaluated ten years ago. It remains unaccounted.

6. A greater role for genomics in the evaluation and potential management of patients

Ten years ago, the human genome had not been mapped. Now, it has, and the information generated is referred to by some as the "new anatomy."11 With the mapping and sequencing of the human genome, medical professionals from essentially all specialties have turned their attention to investigating the role genes play in health and disease, and genetic disease represents an important part of medical practice. Diagnosing a genetic disorder not only allows for disease-specific management options but also has implications for the affected individual's entire family. As such, a working understanding of the underlying concepts of genetic disease is necessary for today's practicing physician, and routine clinical practice requires integration of these fundamental concepts for use in accurate diagnosis and ensuring appropriate referrals for patients with genetic disease and their families.12

In addition, genomic information will become integral to the selection of treatment in a variety of disease conditions, adding a new dimension to disease management.13 All of this expands the knowledge base required for each E/M service since this information must be integrated with the traditional cognitive base.

II. The intensity of E/M services has increased over time.

Support for the increased intensity of E/M services, particularly office visits, may be found in the results of the National Ambulatory Medical Care Survey. Data from this survey published by the Centers for Disease Control and Prevention in 2003 reflect increasing complexity and intensity of physician work in office practice from 1992-2002. Patients were older, had more complex diagnoses, more discussion of treatment and more mention of drugs used in treatment in 2002 than was the case in 1992.14

Yet, coding patterns for office visits have not changed substantially in that time. In its August 2002 report to the CPT Editorial Panel, the CPT E/M Services Work Group, of which CMS was a part,

referenced an analysis of Medicare claims reporting data for E/M services within selected specialties from 1992-2000. The aggregate data, provided by CMS staff, suggested stability in use of the E/M visit codes by physicians. In particular, the data showed a stable pattern in reporting of services by major users of E/M codes, such as internists, family physicians, neurologists, and cardiologists,. This suggests that physicians have not attempted to capture the increased intensity of their work by choosing higher level E/M codes to report their services. Though the intensity of a given level of E/M service has increased since the last time these codes were reviewed, physicians have maintained internally consistent relative value of service (i.e. the proportion of visits at each level as remained stable though there is clearly more work involved at each level).

III. Hospital length of stay has changed.

Hospital length of stay has decreased in the last ten years. According to Medicare data, in 1990, the average length of stay in all short-stay hospitals was 9.0 days. In 2001, the corresponding length of stay was 6.0 days.15,16

Shortened length of stay has been accomplished with the combined efforts of hospitals, insurance carriers, and home care service companies and the effective and rapid use of new diagnostic tests and powerful new therapies. The orchestration of all this care, however, requires the intense efforts of physicians in the inpatient setting.

Some of this care is provided by hospitalists. The emergence of the hospitalist as a specialist in inpatient medicine is another change in medical care that has occurred in the last ten years. Hospitals, health systems and health maintenance organizations have used hospitalists as a means to reduce length of stays and more efficiently manage inpatient care.17 Their success in doing so is unclear.18 However, to the extent that the use of hospitalists has had an impact on hospital length of stay and medical practice, that impact on the work associated with E/M services remains unmeasured.

The impact of shorter lengths of stay is compounded by and compounds other changes that we have described. For instance, we believe that patients are more complex upon admission due to such factors as more chronic illnesses and polypharmacy. In turn, shorter lengths of stay may mean that patients are sicker and more complex on discharge, which potentially affects both hospital discharge services and the complexity of services in the outpatient setting. All of this has implications for the work of E/M services in the inpatient setting which must, therefore, be reviewed during the five-year review.

Other Reasons for Reviewing the E/M Codes

I. Relative Intensity of E/M

During the first five-year review, CMS agreed that the E/M services were undervalued relative to most other services, based on a comparison of intensity (i.e., intraservice work per unit of time (IWPUT)). IWPUT is calculated by dividing the work RVUs attributable to the interservice period by the intraservice time in minutes. We believe a comparison of current IWPUT for E/M codes and other

CMS-1429-FC-036

December 23, 2004

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8012

Submitted electronically at http://www.cms.hhs.gov/regulations/ecomments

Dear Dr. McClellan:

The American Association of Geriatric Psychiatrists (AAGP) is pleased to submit these comments related to the November 15, 2004 Federal Register publication of the Final Rule with Comment Period for Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005. The AAGP is a professional membership organization dedicated to promoting the mental health and well-being of older people and improving the care of those with late-life mental disorders. Our membership consists of more than 2,000 geriatric psychiatrists as well as other health care professionals who focus on the mental health problems faced by senior citizens.

Five Year Refinement of Work Relative Value Unites for Calendar Year 2004
The AAGP joins the American Medical Directors Association (AMDA), the American Association of Home Care Physicians (AAHCP) and a coalition of primary care organizations in requesting that nursing facility services (CPT 99301-99313) and domiciliary services (CPT 99321-99333) be included among the services whose work values will be re-examined during the upcoming five-year review. In making this request, we want to emphasize, as AMDA and AAHCP will separately, that this re-examination of work values should be based upon the coding schema recently recommended for these services by AMDA and AAHCP.

For nursing facility services, the recommended coding schema would involve the following changes to the Nursing Facility Services section of CPT:
* Revise the structure of the current Comprehensive Nursing Facility Assessment codes to create three levels of service for admissions, consistent with the structure of the three levels of service for admission in the Initial Hospital Care section of CPT;

* Add a fourth level of service to the Subsequent Nursing Facility Care codes to allow the reporting of a comprehensive level of care (comprehensive history, comprehensive exam, high complexity decision making; and,
* Add a new code in a new subsection (Other Nursing Facility Care) to allow the reporting of a comprehensive annual assessment.

For domiciliary services, the recommended coding changes to the Domiciliary Services section of CPT would be as follows:
* For new patients, the addition of two, more comprehensive levels of service to the existing three levels of service, with modifications to the descriptors for the latter.
* For established patients, the addition of one more comprehensive level of service to the existing three levels of service, with modifications to the descriptors for the existing codes.

Taken together, these recommended coding changes for domiciliary services would produce a set of codes comparable to the current one for home services (CPT 99341-99345 and CPT 99347-99350. Rather than repeat the rationale and data cited by AMDA, AAHCP and other organizations in support of requested work value increases for nursing facility and domiciliary services, AAGP would simply like to emphasize a few key points.

In the case of nursing facility services, the Nursing Home Component of the 1996 Medical Expenditure Panel Survey (MEPS) and the Institutional Population Component of the 1987 National Medical Expenditure Survey (NMES) provide ample evidence of the increasing age and disability of nursing home residents. For example, the mean age for elderly residents (those 65 and over) increased from 83.5 years in 1987 to 84.6 years in 1996. And nursing home residents were more functionally disabled in 1996 than in 1987. By 1996, 82.9 percent of nursing home residents received assistance with three or more activities of daily living, a 15.5 percent increase over the comparable figure in 1987. Further close to half of all nursing home residents (47.7 percent)—and more than half of those 85 and over (53.6 percent)--had some form of dementia in 1996. And nearly three-quarters of them (70.8 percent) had some form of memory loss, short-term, long-term, or both. Depression was found to be the 6th most frequently occurring medical condition, affecting slightly more than 20 percent of all nursing home residents. Unfortunately, as noted by Bartels, Moak and Dums (in “Models of Mental Health Services in Nursing Homes: A Review of the Literature,” Psychiatric Services 53(11):1390-1396, 2002), “[d]espite the high prevalence of psychiatric and behavioral problems among nursing home residents, most of those residents who need mental health services do not receive them.”

In the case of domiciliary care facilities, including assisted living facilities (ALFs), many of their residents have psychiatric problems or Alzheimer’s disease and related disorders complicated by psychiatric and behavioral disturbances. These problems often complicate and compromise the management of their medical illnesses and increase the risk of institutional placement. Effective management of psychiatric and behavioral problems usually requires a complex and work-intensive coordination of medical treatment, environmental manipulation including liaison with facility staff, and education and counseling of family members. Spillman, Liu and McGilliard, in their November 25, 2002 report Trends in Residential Long-Term Care: Use of Nursing Homes and Assisted Living and Characteristics of Facilities and Residents, prepared for the Office of the Assistant Secretary for Planning and Evaluation of the U.S. Department of Health and Human Services, documented the increasing age and disability of ALF residents. For example, the proportion of ALF residents age 85 and older went from 44.8 percent in 1992 to 50.4 percent in 1998. The proportion of ALF residents showing impairment in 3 or more activities of daily living rose from 34.6 percent to 52.1 percent over this same

time period. Finally, the proportion of ALF residents reporting their health as excellent or very good declined from 26.0 percent to 11.5 percent.

Another important reason for reviewing the current work values for the domiciliary services is that these values were not based on survey results and they have never been subjected to a full review by the AMA's Specialty Society Relative Value Update Committee (RUC).

In light of the above information and the additional arguments being made by AMDA, AAHCP and a coalition of primary care organizations, we believe there is more than enough justification to review the work values for both nursing facility and domiciliary services during the upcoming five-year review of relative values. We look forward to working with CMS, the RUC and other physician organizations to assure the proper valuation of these important services.

Sincerely,

Christine M. deVries
Executive Director

CMS-1429-FC-037

December 27, 2004
Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, D.C. 20201

Re: CMS-1429-FC (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005)

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) final rule with comment period regarding revisions to payment policies under the Medicare physician fee schedule, published in the Federal Register on November 15, 2004 (the "Final Rule").1 BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

Representing an industry that is devoted to discovering new cures and ensuring patient access to them, BIO continues to be concerned that the major reimbursement changes mandated by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) will have serious ramifications for patients. That being said, we are pleased by CMS' statements in the Final Rule that the agency will continue to monitor patient access through the 1-800-Medicare line, the regional office staff, claims analysis, and other environmental scanning activities. We commend the agency for agreeing to work with Congress should any access issues occur.2 Moreover, we believe that CMS' adoption of the new drug administration codes and the initiation of a demonstration project on improved quality of care for cancer patients undergoing chemotherapy will go a long way to help ensure that Medicare patients continue to have access to the critical and potentially life-saving therapies they need. This goal is more likely to be realized if CMS waives the beneficiary coinsurance for the demonstration project.

Other policies adopted by CMS in the Final Rule also will help ensure beneficiary access to care. Reimbursing for the ten top separately billable end stage renal disease (ESRD) drugs and biologicals at the weighted average of the actual acquisition costs of both large and small dialysis providers as determined by the Office of Inspector General (IG) and updated by the Producer Price Index (PPI) is appropriate and properly implements the statute. Similarly, the increase in the furnishing fee for blood clotting factor from $0.05 per unit to $0.14 per unit will much more adequately reimburse providers and ensure patient access to this life-saving therapy. Finally, we applaud CMS for increasing the per prescription supplying fee from the proposed $10 per prescription to $24 and implementing the proposed

common sense reforms to the billing requirements and shipping time frames.

Although we appreciate CMS' clarification in the Final Rule regarding payment rates for new drugs and biologicals until a rate based on average sales price (ASP) can be implemented, we are deeply concerned that payment at wholesale acquisition cost (WAC) could jeopardize patients' access to new therapies. Accordingly, we urge the agency to pay for these single source drugs and biologicals at 95% of their average wholesale price (AWP) or at a rate appropriate to ensure beneficiary access to them. We also urge the agency to give manufacturers the guidance they need to submit accurate ASP data to the agency. Until all questions are answered thoroughly, payment rates will not be accurate. We particularly ask that CMS detail the process manufacturers should use to correct erroneous filings. This has been particularly important in light of the recent clarification the agency issued with respect to bona fide service fees.3 In addition, we reiterate our requests for the agency to release ASP-based rates promptly each quarter and to have all calculations confirmed by an outside auditor. The list of the national drug codes (NDCs) considered in setting the rate for each health care common procedural coding system (HCPCS) code has been very helpful. These issues are discussed in detail below.

I. ASP Payment Methodology

A. Patient Access

As we discussed in depth in our comments to the proposed rule,4 patients' access to biological therapies is dependent both on adequate reimbursement for the therapies themselves as well as adequate reimbursement for the unique costs of handling, administering, and preparing them. In implementing the payment reforms required by section 303 of the MMA, we urged CMS to put beneficiaries first. We also asked the agency to monitor patient access issues proactively and to establish simple mechanisms by which beneficiaries and providers could easily report access issues. We are particularly concerned about beneficiary access for patients with rare diseases and conditions.

BIO is pleased that CMS addressed this issue in the Final Rule and that the agency is committed to monitoring access issues through the 1-800-Medicare line, the regional office staff, claims analysis, and other environmental scanning activities.5 We also appreciate that the agency is willing to work with Congress should any access issues occur. We hope CMS will use its website as an additional mechanism to collect data regarding problems with patient access. Moreover, we urge the agency to educate beneficiaries about the availability of the 1-800-Medicare number and website form to register concerns and complaints about access issues. Unless beneficiaries know that these avenues exist to give feedback, CMS will not be able to collect the information it needs to fully evaluate access issues.

B. Need for Additional ASP Guidance

For ASP-based payment rates to be appropriate, manufacturers must obtain the guidance they need to submit accurate data. We raised numerous questions in our comments to the proposed rule6 as well as to the Interim Final Rule on ASP data submissions7 that the agency has not yet answered. We urge CMS to give these issues the immediate attention that they deserve, particularly now that payment rates are being set based on these ASP data. We do appreciate the agency's recent clarification regarding

bona fide service fees.8

Some of our members would like to correct their filings based on this new information or for other reasons. We urge CMS to provide prompt guidance on the process manufacturers should use to correct erroneous filings. Specifically, we seek detailed answers to the following questions:

1) Where should manufacturers send corrections?
2) How will the receipt of corrected information be confirmed?
3) How quickly will corrections be reflected through revised payment rates?
4) Will reimbursements that occurred prior to the correction be modified?
5) Does CMS intend to hold providers harmless for any overpayments made prior to the correction?

We urge the agency to answer these questions – as well as the others we have posed in prior comments – without delay.

C. Calculation and Release of ASP-Based Payment Rates

BIO commends the agency for recognizing the need "to provide as much information on Medicare Part B drug payment rates as possible as early as possible prior to the effective date of those rates."9 We are deeply concerned, however, that the actual release of the rates on December 17 – a mere two weeks before they actually become effective – does not meet this goal. As we discussed in our comments to the proposed rule, these calculations are complicated and errors inevitably will occur. Releasing the payment rates promptly will allow manufacturers and other interested parties to have a few weeks before the rates become effective to identify errors and will give CMS ample time to correct them before they actually go into effect. This is particularly important because, as noted above, there is no clear process for working with the agency to resolve errors in released ASP figures before the rates go into effect.

We urge CMS to release future payment rates at least a month before they become effective and to establish a process for correcting rates before their effective date. Part of this process should be the establishment of a task force or other mechanism to which a manufacturer or other interested party could go for a quick resolution regarding a potential error. We also would appreciate some assurance from the agency that it is using an external auditor or some other mechanism to verify rates are properly calculated. BIO appreciates CMS' release of the list of NDCs associated with each HCPCS code. This information has been helpful in attempting to better understand the agency's calculation of ASP-based rates.

D. Payment Methodology in Cases Where the ASP During the First Quarter of Sales in Unavailable

Section 1847A(c)(4) of the Social Security Act (SSA) states, "In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on – (A) the wholesale acquisition cost; or (B) the methodology in effect under this

part on November 1, 2003, to determine the payment amounts for drugs or biologicals." The Final Rule clarifies that CMS will pay on this basis for a limited period of time, starting "on the date that sales of the drug begin and end[ing] at the beginning of the quarter after [the agency] receives data from the manufacturer regarding ASP for the first full quarter of sales."10 We appreciate CMS' acknowledgement in the Final Rule that this period may last during the product's second full quarter of sales when the manufacturer's ASP has been reported but is not yet in use.

After seeing the recently released payment rates for these products whose ASPs are unavailable, it appears that CMS has set payment rates at WAC rather than based on WAC or the methodology in effect on November 1, 2003 (i.e. 95% of AWP). BIO is deeply troubled that reimbursement at WAC may deny beneficiaries access to new therapies. Section 1847A(c)(6)(B) defines WAC as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, . . . as reported in wholesale price guides or other publications of drug or biological pricing data." We believe that the price at which wholesalers purchase a drug or biological from manufacturers is not an appropriate reimbursement rate for physicians because they are unlikely to be able to purchase drugs and biologicals from wholesalers for this amount. This is why the statute specifies that payment for existing drugs and biologicals is at the lesser of 106% of ASP or 106% of WAC.11 We believe that the later reference to payment for new drugs should be read to mean 106% of WAC.

BIO requests that CMS exercise its clear statutory authority to set reimbursement rates for single source products whose ASPs are unavailable at 95% of AWP or at a rate appropriate to ensure beneficiary access to them. New drugs without unique HCPCS codes are paid at 95% of AWP in the hospital outpatient prospective payment system, and payment at this amount would equalize payment across settings and not create economic incentives to treat patients needing new drugs in the hospital outpatient department setting instead. We urge CMS to act within its statutory discretion and ensure adequate reimbursement for these therapies. Unless payment rates are adequate, patients will not have access to cutting-edge therapies that may provide their best hope for treatment.

E. Payment for Drugs Furnished During 2005 if Separately Billed by Renal Dialysis Facilities

The Final Rule determines that separately billable ESRD drugs will be paid based "on the actual dollar value of the acquisition costs as determined by the IG rather than the acquisition costs relative to ASP,"12 updated by the PPI for prescription preparations. Payment amounts will be based on a weighted average of acquisition costs of the for largest providers and the other facilities. For drugs and biologicals not studied by the IG, payment will be ASP plus 6%.13 BIO applauds this decision because it properly implements the statute and will help ensure beneficiary access to critical ESRD therapies.

II. Drug Administration Payment Policy and Coding Effective in 2005

Section 1848(c)(2)(J)(i) of the SSA requires the Secretary to "promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption." The statute

also specifies that the Secretary use existing processes for considering these coding changes and establishing relative values for them.14 In the Final Rule, CMS adopted the drug administration coding changes made by the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel, using G-codes so that the changes will be effective in 2005.15 The agency also adopted the practice expense resource inputs and work relative values as recommended by the AMA's Relative Value Update Committee (RUC).16 BIO applauds CMS' willingness to adopt these coding changes as recommended by the AMA. We believe these changes will go a long way to help ensure beneficiary access to critical drug and biological therapies by reimbursing physicians more appropriately for the important services they perform as well as for the practice expenses they incur. We particularly appreciate the acknowledgment that the administration of certain biologicals is as complex and resource consuming as the administration of chemotherapy agents.

BIO also appreciates CMS' prompt guidance to contractors regarding the 2005 drug administration coding revisions.17 As the December 10, 2004 transmittal on this topic states, "For services furnished on or after January 1, 2005, chemotherapy administration codes apply to parenteral administration of nonradionuclide anti-neoplastic drugs and also to anti-neoplastic agents provided for the treatment of noncancer diagnoses . . . or to substances such as monoclonal antibody agents and other biologic response modifiers." Although we appreciate that CMS has listed some therapies "commonly considered to fall under the category of monoclonal antibodies" and that always should be assigned to the new chemotherapy code, we encourage the agency and its contractors not to create any single exhaustive list. Indeed, by including the language "such as" in the description, the AMA did not limit the list of therapies eligible for inclusion under the chemotherapy administration codes to monoclonal antibodies and biologic response modifiers or any other particular type of drug. Instead, payers should be encouraged to examine the complexity and resources required to administer each individual drug or biological to determine the appropriate administration code. The test should be whether the physician work and practice expense to administer the therapy is consistent with the new code. It is with this understanding that we hope carriers "provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare."18

In addition to the changes for drug administration services, BIO believes the demonstration of improved quality of care for cancer patients undergoing chemotherapy will help ensure beneficiary access to appropriate care. In the final rule, CMS announced a demonstration project to "identify and assess certain oncology services in an office-based oncology practice that positively affect outcomes in the Medicare population."19 The demonstration project, created pursuant to the Secretary's authority under sections 402(a)(1)(B) and 402(a)(2) of the SSA Amendments of 1967,20 will pay participating providers $130 per encounter to collect data on the patient's levels of pain, nausea or vomiting, and fatigue. CMS plans to use the data to "determine ways to improve the quality of care and quality of life" for beneficiaries with cancer.21 This demonstration project could help ensure Medicare beneficiaries' access to critical therapies today and improved quality of care in the future.

BIO is concerned, though, that the demonstration's coinsurance burden will discourage many beneficiaries from participating. CMS has said that the usual Part B deductible and coinsurance apply to the demonstration project,22 meaning that beneficiaries will be liable for $26 in coinsurance for each

chemotherapy administration encounter, in addition to the coinsurance for the drugs and other services provided. For beneficiaries who receive several rounds of chemotherapy, participating in the demonstration could increase their out-of-pocket costs by hundreds of dollars. Many beneficiaries may choose not to participate rather than pay the additional coinsurance, defeating the purpose of the demonstration project by denying CMS the opportunity to collect important data. The coinsurance burden also places providers in the difficult position of asking their patients to pay for CMS' data collection efforts, even though the patients will not receive additional services.

To ensure that Medicare beneficiaries receive optimal care today and in the future, we recommend that CMS waive the coinsurance requirement for this demonstration. CMS has the authority to waive this requirement under section 402(b) of the SSA Amendments of 1967,23 allowing the Secretary to waive Medicare's usual payment requirements in demonstration programs. Relieving beneficiaries of the coinsurance burden would facilitate greater participation by cancer patients and would allow CMS to collect data from all Medicare beneficiaries undergoing cancer treatment.

III. Blood Clotting Factor

For blood clotting factor supplied on or after January 1, 2005, CMS had proposed to establish a separate payment of $0.05 per unit to hemophilia treatment centers, homecare companies, and other suppliers for the items and services associated with the furnishing of blood clotting factor. BIO was deeply concerned that this amount would not be adequate to protect beneficiary access to these critical therapies, especially in light of payment cuts for clotting factor therapies. The Final Rule increases this amount to $0.14 per unit of clotting factor in 2005.24 For years after 2005, the MMA specifies that the furnishing fee be updated by the percentage increase in the consumer price index for medical care for the 12-month period ending with June the previous year. BIO appreciates CMS' willingness to increase the furnishing fee to a reasonable amount and believes this will go a long way to help ensure that Medicare patients with hemophilia are able to access the care they need.

IV. Supplying Fee, Billing Requirements, and Shipping Time Frame

Similarly, the Final Rule increases the supplying fee to pharmacies for immunosuppressive drugs and oral anticancer drugs and anti-emetics from the proposed $10 per prescription to $24.25 CMS also establishes a higher supplying fee of $50 for the initial oral immunosuppressive prescription in the first month after a beneficiary has a transplant "because the costs of supplying immunosuppressives are likely to be higher immediately following a transplant, when the practitioner is adjusting the dose of immunosuppressive drugs."26 BIO applauds CMS for increasing the supplying fee and believes such an increase was imperative to ensure beneficiary access to these critical therapies. We also appreciate the common sense reforms the agency has made to the billing requirements and shipping time frames.27 These reforms will eliminate some of the paperwork and delays associated with obtaining payment for these therapies and will help reduce pharmacies' administrative expenses.

V. Conclusion

In sum, BIO continues to be concerned that the major reimbursement changes created by section 303 of the MMA will have serious ramifications for patients and urges CMS to make patient access the agency's primary focus as it implements this section. In light of this goal, we are pleased by the substantial improvements CMS has made in the Final Rule. Specifically, we appreciate the agency's recognition of the importance of actively monitoring patient access as the reforms are implemented and believe that the adoption of the new drug administration codes and the demonstration of improved quality of care for cancer patients undergoing chemotherapy will help improve beneficiaries' access to care. Reimbursing for the top ten separately billable ESRD drugs and biologicals at the weighted average of the actual acquisition costs of both large and small dialysis providers as determined by the IG and updated by the PPI, increasing the furnishing fee for blood clotting factor from $0.05 per unit to $0.14 per unit, and increasing the per prescription supplying fee from the proposed $10 per prescription to $24 also will help ensure that Medicare beneficiaries will have access to the care they need.
There are some shortcomings in the Final Rule, however, and we urge CMS to make the following improvements:

* use the website as an additional mechanism to collect data regarding patient access problems and educate beneficiaries about the availability of the 1-800-Medicare number and website form to register concerns and complaints about access issues;
* provide manufacturers with detailed guidance immediately so they can submit accurate ASP data and promptly correct any erroneous filings;
* release future ASP-based rates at least a month before they are effective to give the public an opportunity to identify errors and give the agency an ample opportunity to correct them before they go into effect;

* use an external auditor or some other mechanism to verify that ASP-based rates are calculated properly;
* exercise CMS' clear statutory authority to set reimbursement rates for single source products whose ASPs are unavailable at 95% of AWP or at a rate appropriate to ensure beneficiary access to them; and
* waive the coinsurance requirement for the demonstration of improved quality of care for cancer patients undergoing chemotherapy to encourage widespread participation.

BIO appreciates the opportunity to comment on the important issues raised in the Final Rule, and we look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact Jayson Slotnik at (202) 312-9273 if you have any questions. Thank you for your attention to this very important matter.

Respectfully submitted, S/

Michael Werner,
Chief of Policy

1 69 Fed. Reg. 66236 (Nov. 15, 2004).
2 Id. at 66300.

3 Letter from Herb B. Kuhn, Director, Center for Medicare Management, CMS, to John Gray, President and CEO, Healthcare Distribution Management Association, and Steve Collis, President, Specialty Biotech and Distributors Association, dated December 9, 2004.
4 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS, dated September 24, 2004.
5 69 Fed. Reg. at 66300.
6 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS, dated September 24, 2004.
7 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS, dated June 7, 2004.
8 Letter from Herb B. Kuhn, Director, Center for Medicare Management, CMS, to John Gray, President and CEO, Healthcare Distribution Management Association, and Steve Collis, President, Specialty Biotech and Distributors Association, dated December 9, 2004.
9 69 Fed. Reg. at 66300.
10 69 Fed. Reg. at 66302.
11 SSA § 1847A(b)(1)(B).
12 Id.
13 Id.
14 SSA § 1848(c)(2)(J)(ii).
15 69 Fed. Reg. at 66303.
16 Id.
17 CMS Program Transmittal 129 (Change Request 3631), One-Time Notification, "2005 Drug Administration Coding Revisions" (Dec. 10, 2004).
18 Id.
19 69 Fed. Reg. at 66308.
20 Pub. L. No. 90-248, codified at 42 U.S.C. § 1395b-1.
21 69 Fed. Reg. at 66309.
22 CMS Manual System, Pub. 100-19 Demonstrations, Change Request 3634, Chemotherapy Demonstration Project, Dec. 10, 2004, available at http://www.cms.hhs.gov/manuals/pm_trans/R12DEMO.pdf.
23 42 U.S.C. § 1395(b).
24 69 Fed Reg. at 66311.
25 Id. at 66313.
26 Id.
27 Id. at 66314

CMS-1429-FC-038

December 27, 2004

Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, D.C. 20201

Re: Comments on Final Rule [Docket No. CMS-1429-FC]: Medicare Program; Payment Reform for Part B Drugs

Dear Dr. McClellan:

The Infectious Diseases Society of America (IDSA) welcomes the opportunity to comment on the 2005 Physician Payment Schedule Final Rule (final rule) published on November 15, 2004. This has been a challenging year for both CMS and the specialty societies, including IDSA, due to implementation deadlines related to the passage of the 2003 Medicare Modernization Act (MMA).

IDSA appreciates the time CMS staff has devoted to the MMA's implementation, including the restructuring of drug infusion and injection codes and the establishment of a drug reimbursement plan based on the average sales price (ASP). IDSA also appreciates CMS's acceptance of some of our recommendations on the proposed rule. However, IDSA is deeply troubled by the difficult position the final rule has created for infectious diseases physicians and their patients. We are eager to work with CMS to find solutions. However, until such solutions have been found, IDSA believes that CMS should withdraw the flawed ASP payment program. With this in mind, IDSA will comment on the following issues:

CMS should withdraw the ASP payment program until critical methodological, patient access, and implementation issues are addressed.

* CMS' ASP methodology is flawed resulting in dangerous cost/payment imbalances for many infectious diseases drugs/biologics, including many antibiotics.
* The 25% drop in reimbursements for infectious diseases-related drugs is likely to cause immediate access problems for patients suffering from infectious diseases.
* The relative value units (RVUs), and most notably, for diagnostic and therapeutic infusions need to be increased to better reflect physician costs involved in administering these infusions.
* CMS must provide additional leadership and guidance.
* CMS must develop contingency plans immediately to prevent what may become a patient access catastrophe starting on January 1, 2005.

Vaccinations

* All seven adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) should be covered under the Physician Fee Schedule. The 2005 Physician Fee Schedule only covers vaccinations for pneumococcal, influenza, and hepatitis B.

Sustainable Growth Rate

* CMS must act to remove Part B drugs from Sustainable Growth Rate (SGR) formula.

BACKGROUND

IDSA represents more than 8,000 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases. The Society's members focus on the epidemiology, diagnosis, investigation and treatment of infectious diseases as well as strive to prevent them in the U.S. and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, those with cancer or transplants who have life-threatening infections caused by unusual microorganisms, food poisoning, and HIV/AIDS as well as new and emerging infections, such as severe acute respiratory syndrome (SARS). Housed within IDSA is the HIV Medicine Association (HIVMA), which represents more than 2,600 physicians working on the frontline of the HIV/AIDS pandemic. HIVMA members conduct research, administer prevention programs and provide clinical services to individuals with HIV disease. Together, IDSA and HIVMA are the principal organizations representing ID and HIV physicians in the United States.

ASP PAYMENT PROGRAM IS NOT READY FOR IMPLEMENATION

Effective January 1, 2005, in accordance with section 303 of the MMA, CMS plans to implement its ASP payment program for covered prescription drugs. This significant new payment structure will have serious implications for infectious diseases (ID) physicians and their seriously ill patients. It is readily apparent that the new ASP system is not yet ready to be implemented. CMS delay in publishing 3rd Quarter 2004 ASP rates is but one example of how the government is disregarding common sense to prematurely implement this new payment program. Rushing the implementation of this complex new pay structure when CMS is not yet ready is a disservice to both the nation’s elderly and disabled and the many physicians who serve them. CMS should withdraw the flawed ASP payment system until critical methodological, patient access, and implementation issues are addressed. At the very least, CMS must develop contingency plans immediately to avoid a patient access catastrophe in 2005.

Better Methodology Needed

CMS needs to employ a better methodology for assessing the accuracy and appropriateness of ASP data that it collects from pharmaceutical companies. CMS’ current methodology is flawed as it does not consider that physicians often purchase drugs/biologics from wholesalers, etc. and not directly from drug companies. CMS flawed methodology also does not consider the additional drug costs that physicians incur such as drug shipping costs, inventory maintenance, and storage. Moreover, the quarterly delays between the time ASP data is collected from companies and the time physicians purchase the drugs to treat patients places physicians in significant financial risk. The current methodology is producing results that are significantly different than physicians’ actual costs, and physicians will be not administer drugs and biologics that are money losers.

Negative Impact For Infectious Diseases Patients and Physicians
In CMS' own estimate provided in Table 43 of the final rule, drug reimbursements for infectious diseases drugs/biologics will be cut by 25%. This is in addition to the one-third drop in the reimbursement for providing non-chemotherapy infusions, which will take effect January 1, 2005. On December 20, 2004, in follow-up to the final rule, CMS released 3rd Quarter 2004 ASP rates upon which 1st Quarter 2005 reimbursements will be made. The ASP + 6% payment rates issued by CMS will result in drug reimbursements that are drastically below what ID specialists are paying for these drugs and biologics (see Table 1). These imbalances have spurred hundreds of questions by ID physicians, including what they should do to prevent access problems for Medicare beneficiaries in their local areas. Care for many of these beneficiaries is likely to be shifted back to skilled nursing facilities and hospitals where the cost of their treatments and care will be significantly greater than in physicians' offices. The exact impact on patients in terms of medical risk, disruption of lives, and financial impact is yet unknown, but may be severe. CMS must devise a better system to ensure the appropriateness and accuracy of its ASP methodology upon which drug/biological payment rates will be based.

Table 1: Drugs Commonly Used by Infectious Disease Doctors (Bold indicates strong likelihood of future patient access problems)
J Code
Name
Medicare payment rates 1/1/2004
Medicare payment rates 1/1/2005 Drug Prices 3rd Quarter 2004 (ASP+6%)

ASP or WAC What Select Physicians are Paying J0285 Amphotericin B 50mg $9.30 $10.28
WAC
$8.25
J0289
Amphotericin B-lipid 10mg
$32.03
$35.80
ASP
$32.84
J0637
Caspofungin 5mg
$29.48
$31.88
ASP
$31.25
J0696
Ceftriaxone 250mg
$13.35
$6.57
ASP

$6.82
J0713
Ceftazidime 500mg
$6.05
$3.74
ASP
$5.99
J0878
Daptomycin 500mg
$153.32
$140.00
ASP
$135.83
J1335
Ertapenem inj. 500mg
$21.24
$21.30
ASP
$20.33
J1563
IVIG, injection **1gram
$66.00
$40.02
ASP
$49.00
J1580
Gentamicin (up to 80mg)
$1.70
$1.44
ASP
$0.68
J1745
Infleximab (Remicade) 10mg
$58.79
$53.08
ASP
$52.30
J1956
Levofloxacin 250mg
$18.62
$7.64
ASP
$16.62

J2185
Meropenem 100mg
$4.40
$3.40
ASP
$4.81
J2543
Piperacillin/tazobactam 1.125gm
$4.36
$4.59
ASP
$5.41
J3260
Tobramycin (up to 80 mg)
$3.99
$1.98
ASP
$1.85
J3370
Vancomycin 500mg
$2.57
$2.98
ASP
$2.01

Many of the drugs and biologicals that ID specialists infuse will be significantly negatively affected under the existing ASP methodology. Examples of ID drugs for which significant cost/payment imbalances have been created include meropenem, vancomycin, levofloxacin, etc. (see Table 1, particularly bolded information). Intravenous immunoglobulin (IVIG) also is severely impacted. IVIG is the only effective treatment for primary immunodeficiency disease. In addition, IVIG is used for the treatment of Kawasaki's disease, in conjunction with bone marrow transplantation, and to treat idiopathic thrombocytopenic purpura. For some patients, IVIG is a lifesaving treatment and thus continued access to the product in 2005 is vital. This is unlikely to occur under the drastic cuts that IVIG will sustain due to the transition to the flawed ASP methodology.

Infectious Diseases Drug Administration RVUs

In addition, the 2005 physician fee schedule rule reflects a continued disconnect between the RVUs, and most notably practice expense RVUs, used to calculate reimbursements for non-chemotherapy drug infusion codes (new codes, G0347, G0348, G0349, G0350) and the actual physician costs in administering these infusions. This disparity combined with the ASP+6% drug cost/payment imbalance will make it increasingly difficult for many infectious diseases physicians to offer infusion services to Medicare beneficiaries. In order to prevent this outcome, the RVUs for non-chemotherapy infusions must be increased to better reflect infectious diseases physician's costs in administering these infusions. The extraordinary work of the AMA CPT Editorial Panel and the RVS Update Committee in 2004 in

preparing these codes should be applauded. Unfortunately, the process was not fully successful as it provided inadequate reimbursement recommendations for the costs associated with antibiotic infusions and some biological infusions.

Additional CMS' Leadership and Guidance is Needed

CMS tacitly acknowledged its own fear that the cost/payment imbalance prompted by the implementation of the ASP program will create access problems for Medicare beneficiaries when it increased payments to oncologists through a $300 million "One Year Demonstration Project". CMS created no similar safeguarding mechanism to protect access to antibiotics for elderly and disabled patients suffering from serious infectious diseases. CMS should work with all specialty societies (not only oncologists) to ensure Medicare beneficiaries have adequate access to essential medicines.

In addition, Medical specialties and physicians have raised numerous questions to CMS about how the newly restructured ASP methodology and drug administration codes are to be implemented. Physicians have asked about which biologics are to be billed under which infusion codes (chemo vs. non-chemo) and how physicians are to participate in volume discount purchasing plans that currently do not exist. CMS officials have continued to promise the issuance of guidance, but such guidance has not materialized. IDSA understands that the passage of the Medicare Modernization Act (MMA) passed in 2003 greatly expanded CMS' workload. However, specialty societies cannot and should not be expected to answer questions devoid of CMS guidance. CMS should work with all specialty societies to find answers to the tough questions it is being asked, including how to ensure infectious diseases physicians can find drugs/biologics at prices below ASP+6.

Post-Quarter Realignment to Avoid Patient Access Issues

Should CMS move forward with its current ASP methodology, a contingency plans is needed to avoid patient access issues. There are several solutions that can be incorporated temporarily into the ASP methodology. One solution would be to establish a process whereby physicians would on a quarterly basis submit the necessary paperwork demonstrating that the drug payment rates CMS is employing for certain drugs were not sufficient to cover physicians drug costs. Physicians would submit the appropriate invoices and CMS would then reimburse the physicians the difference.

VACCINES

The development of vaccines and the enforcement of vaccination programs have been among the leading preventatives against death and debilitating diseases over the last 50 years. Vaccinations are usually associated with preventing childhood diseases but they also play a significant role in sustaining a healthy adult population. According to the Advisory Committee on Immunization Practices (ACIP), adults should have up-to-date vaccinations for the following conditions: pneumonia, influenza, hepatitis A, hepatitis B, tetanus, varicella (chickenpox), and meningitis. The 2005 Physician Fee Schedule only covers vaccinations for pneumonia, influenza, hepatitis A & B, and tetanus. While coverage of these five vaccines is an important first step, CMS needs to go much farther by covering all seven adult vaccinations recommended by the ACIP. Additionally, the intranasal flu vaccine should also be covered since it accomplishes the same result as the injected vaccine. Covering all recommended vaccinations, including their oral/intranasal counterparts, through the fee schedule is a sound financial decision since

prevention is more cost effective than treatment.

SUSTAINABLE GROWTH RATE

The SGR system is clearly not sustainable. Flaws in this formula led to a 5.4% payment cut in 2002, and additional cuts in 2003 through 2005 were averted only after Congress intervened. Even with the positive updates the MMA provided, medical practice costs will have increased by 41% from 1991-2005, whereas during the same time period Medicare payments to physicians will have increased by only 18%. CMS must act soon to resolve this continuing problem. It is clear that one of the main factors contributing to this cost/payment disparity is the inclusion of Part B drugs in the SGR formula. CMS should use its administrative authority to remove these drugs from the formula. The ultimate cost of not acting is a gradual but significant reduction in patient access to doctors and in the quality of care they receive over the long term. We can not afford to let this happen.

CONCLUSION

IDSA appreciates this opportunity to comment on CMS Final Physician Fee Schedule Rule. We strongly believe that CMS' ASP methodology is flawed and will result in immediate and significant access problems for patients suffering from infectious diseases. We also believe essential implementation questions have gone unanswered. As such, we urge CMS to withdraw the ASP payment program until critical methodology, patient access, and implementation issues are addressed. If you have any questions concerning this matter, please contact Robert J. Guidos, J.D., IDSA's Director of Public Policy and Government Relations, at 703/299-0200.

Sincerely,

Walter E. Stamm, MD
President

CMS-1429-FC-039

December 27, 2004

Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, D.C. 20201

Re: Comments on Final Rule [Docket No. CMS-1429-FC]: Medicare Program; Payment Reform for Part B Drugs

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IDSA appreciates the time CMS staff has devoted to the MMA's implementation, including the restructuring of drug infusion and injection codes and the establishment of a drug reimbursement plan based on the average sales price (ASP). IDSA also appreciates CMS's acceptance of some of our recommendations on the proposed rule. However, IDSA is deeply troubled by the difficult position the final rule has created for infectious diseases physicians and their patients. We are eager to work with CMS to find solutions. However, until such solutions have been found, IDSA believes that CMS should withdraw the flawed ASP payment program. With this in mind, IDSA will comment on the following issues:

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* The 25% drop in reimbursements for infectious diseases-related drugs is likely to cause immediate access problems for patients suffering from infectious diseases.
* The relative value units (RVUs), and most notably, for diagnostic and therapeutic infusions need to be increased to better reflect physician costs involved in administering these infusions.
* CMS must provide additional leadership and guidance.
* CMS must develop contingency plans immediately to prevent what may become a patient access catastrophe starting on January 1, 2005.

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* CMS must act to remove Part B drugs from Sustainable Growth Rate (SGR) formula.

BACKGROUND

IDSA represents more than 8,000 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases. The Society's members focus on the epidemiology, diagnosis, investigation and treatment of infectious diseases as well as strive to prevent them in the U.S. and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, those with cancer or transplants who have life-threatening infections caused by unusual microorganisms, food poisoning, and HIV/AIDS as well as new and emerging infections, such as severe acute respiratory syndrome (SARS). Housed within IDSA is the HIV Medicine Association (HIVMA), which represents more than 2,600 physicians working on the frontline of the HIV/AIDS pandemic. HIVMA members conduct research, administer prevention programs and provide clinical services to individuals with HIV disease. Together, IDSA and HIVMA are the principal organizations representing ID and HIV physicians in the United States.

ASP PAYMENT PROGRAM IS NOT READY FOR IMPLEMENATION

Effective January 1, 2005, in accordance with section 303 of the MMA, CMS plans to implement its ASP payment program for covered prescription drugs. This significant new payment structure will have serious implications for infectious diseases (ID) physicians and their seriously ill patients. It is readily apparent that the new ASP system is not yet ready to be implemented. CMS delay in publishing 3rd Quarter 2004 ASP rates is but one example of how the government is disregarding common sense to prematurely implement this new payment program. Rushing the implementation of this complex new pay structure when CMS is not yet ready is a disservice to both the nation’s elderly and disabled and the many physicians who serve them. CMS should withdraw the flawed ASP payment system until critical methodological, patient access, and implementation issues are addressed. At the very least, CMS must develop contingency plans immediately to avoid a patient access catastrophe in 2005.

Better Methodology Needed

CMS needs to employ a better methodology for assessing the accuracy and appropriateness of ASP data that it collects from pharmaceutical companies. CMS’ current methodology is flawed as it does not consider that physicians often purchase drugs/biologics from wholesalers, etc. and not directly from drug companies. CMS flawed methodology also does not consider the additional drug costs that physicians incur such as drug shipping costs, inventory maintenance, and storage. Moreover, the quarterly delays between the time ASP data is collected from companies and the time physicians purchase the drugs to treat patients places physicians in significant financial risk. The current methodology is producing results that are significantly different than physicians’ actual costs, and physicians will be not administer drugs and biologics that are money losers.

Negative Impact For Infectious Diseases Patients and Physicians
In CMS' own estimate provided in Table 43 of the final rule, drug reimbursements for infectious diseases drugs/biologics will be cut by 25%. This is in addition to the one-third drop in the reimbursement for providing non-chemotherapy infusions, which will take effect January 1, 2005. On December 20, 2004, in follow-up to the final rule, CMS released 3rd Quarter 2004 ASP rates upon which 1st Quarter 2005 reimbursements will be made. The ASP + 6% payment rates issued by CMS will result in drug reimbursements that are drastically below what ID specialists are paying for these drugs and biologics (see Table 1). These imbalances have spurred hundreds of questions by ID physicians, including what they should do to prevent access problems for Medicare beneficiaries in their local areas. Care for many of these beneficiaries is likely to be shifted back to skilled nursing facilities and hospitals where the cost of their treatments and care will be significantly greater than in physicians' offices. The exact impact on patients in terms of medical risk, disruption of lives, and financial impact is yet unknown, but may be severe. CMS must devise a better system to ensure the appropriateness and accuracy of its ASP methodology upon which drug/biological payment rates will be based.

Table 1: Drugs Commonly Used by Infectious Disease Doctors (Bold indicates strong likelihood of future patient access problems)
J Code
Name
Medicare payment rates 1/1/2004
Medicare payment rates 1/1/2005 Drug Prices 3rd Quarter 2004 (ASP+6%)

ASP or WAC
What Select Physicians are Paying
J0285
Amphotericin B 50mg
$9.30
$10.28
WAC
$8.25
J0289
Amphotericin B-lipid 10mg
$32.03
$35.80
ASP
$32.84
J0637
Caspofungin 5mg
$29.48
$31.88
ASP
$31.25

J0696
Ceftriaxone 250mg
$13.35
$6.57
ASP
$6.82
J0713
Ceftazidime 500mg
$6.05
$3.74
ASP
$5.99
J0878
Daptomycin 500mg
$153.32
$140.00
ASP
$135.83
J1335
Ertapenem inj. 500mg
$21.24
$21.30
ASP
$20.33
J1563
IVIG, injection **1gram
$66.00
$40.02
ASP
$49.00
J1580
Gentamicin (up to 80mg)
$1.70
$1.44
ASP
$0.68
J1745
Infleximab (Remicade) 10mg
$58.79
$53.08
ASP
$52.30
J1956

Levofloxacin 250mg
$18.62
$7.64
ASP
$16.62
J2185
Meropenem 100mg
$4.40
$3.40
ASP
$4.81
J2543
Piperacillin/tazobactam 1.125gm
$4.36
$4.59
ASP
$5.41
J3260
Tobramycin (up to 80 mg)
$3.99
$1.98
ASP
$1.85
J3370
Vancomycin 500mg
$2.57
$2.98
ASP
$2.01

Many of the drugs and biologicals that ID specialists infuse will be significantly negatively affected under the existing ASP methodology. Examples of ID drugs for which significant cost/payment imbalances have been created include meropenem, vancomycin, levofloxacin, etc. (see Table 1, particularly bolded information). Intravenous immunoglobulin (IVIG) also is severely impacted. IVIG is the only effective treatment for primary immunodeficiency disease. In addition, IVIG is used for the treatment of Kawasaki's disease, in conjunction with bone marrow transplantation, and to treat idiopathic thrombocytopenic purpura. For some patients, IVIG is a lifesaving treatment and thus continued access to the product in 2005 is vital. This is unlikely to occur under the drastic cuts that IVIG will sustain due to the transition to the flawed ASP methodology.

Infectious Diseases Drug Administration RVUs

In addition, the 2005 physician fee schedule rule reflects a continued disconnect between the RVUs, and most notably practice expense RVUs, used to calculate reimbursements for non-chemotherapy drug infusion codes (new codes, G0347, G0348, G0349, G0350) and the actual physician costs in

administering these infusions. This disparity combined with the ASP+6% drug cost/payment imbalance will make it increasingly difficult for many infectious diseases physicians to offer infusion services to Medicare beneficiaries. In order to prevent this outcome, the RVUs for non-chemotherapy infusions must be increased to better reflect infectious diseases physician's costs in administering these infusions. The extraordinary work of the AMA CPT Editorial Panel and the RVS Update Committee in 2004 in preparing these codes should be applauded. Unfortunately, the process was not fully successful as it provided inadequate reimbursement recommendations for the costs associated with antibiotic infusions and some biological infusions.

Additional CMS' Leadership and Guidance is Needed

CMS tacitly acknowledged its own fear that the cost/payment imbalance prompted by the implementation of the ASP program will create access problems for Medicare beneficiaries when it increased payments to oncologists through a $300 million "One Year Demonstration Project". CMS created no similar safeguarding mechanism to protect access to antibiotics for elderly and disabled patients suffering from serious infectious diseases. CMS should work with all specialty societies (not only oncologists) to ensure Medicare beneficiaries have adequate access to essential medicines.

In addition, Medical specialties and physicians have raised numerous questions to CMS about how the newly restructured ASP methodology and drug administration codes are to be implemented. Physicians have asked about which biologics are to be billed under which infusion codes (chemo vs. non-chemo) and how physicians are to participate in volume discount purchasing plans that currently do not exist. CMS officials have continued to promise the issuance of guidance, but such guidance has not materialized. IDSA understands that the passage of the Medicare Modernization Act (MMA) passed in 2003 greatly expanded CMS' workload. However, specialty societies cannot and should not be expected to answer questions devoid of CMS guidance. CMS should work with all specialty societies to find answers to the tough questions it is being asked, including how to ensure infectious diseases physicians can find drugs/biologics at prices below ASP+6.

Post-Quarter Realignment to Avoid Patient Access Issues

Should CMS move forward with its current ASP methodology, a contingency plans is needed to avoid patient access issues. There are several solutions that can be incorporated temporarily into the ASP methodology. One solution would be to establish a process whereby physicians would on a quarterly basis submit the necessary paperwork demonstrating that the drug payment rates CMS is employing for certain drugs were not sufficient to cover physicians drug costs. Physicians would submit the appropriate invoices and CMS would then reimburse the physicians the difference.

VACCINES

The development of vaccines and the enforcement of vaccination programs have been among the leading preventatives against death and debilitating diseases over the last 50 years. Vaccinations are usually associated with preventing childhood diseases but they also play a significant role in sustaining a healthy adult population. According to the Advisory Committee on Immunization Practices (ACIP), adults should have up-to-date vaccinations for the following conditions: pneumonia, influenza, hepatitis

A, hepatitis B, tetanus, varicella (chickenpox), and meningitis. The 2005 Physician Fee Schedule only covers vaccinations for pneumonia, influenza, hepatitis A & B, and tetanus. While coverage of these five vaccines is an important first step, CMS needs to go much farther by covering all seven adult vaccinations recommended by the ACIP. Additionally, the intranasal flu vaccine should also be covered since it accomplishes the same result as the injected vaccine. Covering all recommended vaccinations, including their oral/intranasal counterparts, through the fee schedule is a sound financial decision since prevention is more cost effective than treatment.

SUSTAINABLE GROWTH RATE

The SGR system is clearly not sustainable. Flaws in this formula led to a 5.4% payment cut in 2002, and additional cuts in 2003 through 2005 were averted only after Congress intervened. Even with the positive updates the MMA provided, medical practice costs will have increased by 41% from 1991-2005, whereas during the same time period Medicare payments to physicians will have increased by only 18%. CMS must act soon to resolve this continuing problem. It is clear that one of the main factors contributing to this cost/payment disparity is the inclusion of Part B drugs in the SGR formula. CMS should use its administrative authority to remove these drugs from the formula. The ultimate cost of not acting is a gradual but significant reduction in patient access to doctors and in the quality of care they receive over the long term. We can not afford to let this happen.

CONCLUSION

IDSA appreciates this opportunity to comment on CMS Final Physician Fee Schedule Rule. We strongly believe that CMS' ASP methodology is flawed and will result in immediate and significant access problems for patients suffering from infectious diseases. We also believe essential implementation questions have gone unanswered. As such, we urge CMS to withdraw the ASP payment program until critical methodology, patient access, and implementation issues are addressed. If you have any questions concerning this matter, please contact Robert J. Guidos, J.D., IDSA's Director of Public Policy and Government Relations, at 703/299-0200.

Sincerely,

Walter E. Stamm, MD
President

of delirium or dementia, although it can also be associated with mental illness, including depression. As we previously noted, studies show that individuals characterized as being cognitively impaired but not meeting clinical criteria for dementia or Alzheimer's disease have a high risk of progressing to dementia or Alzheimer's disease.[1] Both delirium and dementia have a wide variety of potentially reversible causes, but timely identification and intercession is needed to offset permanent dysfunction. Alzheimer's disease is a progressive degenerative disease characterized by memory problems that eventually lead to severe cognitive and functional impairment. Though there is no cure, treatment is available to help alleviate symptoms and slow the progression of the disease.

Unfortunately, while elderly patients are typically screened for various physical illnesses, busy primary care practitioners often fail to recognize signs of dementia. Though routine screening of patients in whom cognitive impairments are not otherwise suspected is not recommended, USPSTF does make clear that "clinicians should assess cognitive function whenever cognitive impairment or deterioration is suspected, based on direct observation, patient report, or concerns raised by family members, friends, or caretakers.[2] In other words, physicians must be alert to the changes in ordinary functioning and attitude of their elderly patients that may be symptomatic of cognitive dysfunction.[3] If such changes are noted, the USPSTF guidelines states that screening to assess cognitive function is indicated.

We urge CMS to take this historic opportunity to not only reiterate to physicians the importance of being alert to the early warning signs of cognitive dysfunction, but to provide physicians with information about the evidenced-based clinical guidelines that address screening, assessment, diagnosis, and treatment of cognitive dysfunction in the elderly. Such educational efforts could easily be incorporated into CMS' existing provider education strategy for the IPPE. Finally, we believe CMS should state

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[1] Practice Parameter: early detection of dementia: mild cognitive impairment (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. National Guideline Clearinghouse.

[2] U.S. Preventive Services Task Force. Screening for Dementia. Recommendations and Rationale, p.2., available at www.ahrq.gov/clinic/3rduspsf/dementia/dementrr.htm.

[3] Espino *et al*, Diagnostic Approach to the Confused Elderly Patient, American Family Physician available at http://www.aafp.org/alp/980315ap/espino.html. According to experts, the types of changes that may be symptomatic of cognitive dysfunction include such things as: increased difficulty carrying out ordinary daily activities, poor or declining cognitive skills, deterioration in hygiene, health changes such as weight loss, appetite changes, falls, social isolation, loss of interest in customary activities, behavioral and attitudinal changes. These changes, of course, may be indicative of other health issues and diseases including depression. Nevertheless, the only way to rule out cognitive impairment as a cause is to undertake an appropriate screen. *Cooperstein, Screening for Dementia: Cerebral Dysfunctioning in the Elderly*, available at http://www.expertlaw.com/library/attyarticles/dementia.html.

unequivocally, that a physician is obliged to screen a Medicare beneficiary for cognitive function and mental status if, as a result of the IPPE, functional, physical, or attitudinal changes indicative of cognitive dysfunction are identified.

Again, we thank you for the opportunity to provide comments on the final rule implementing the IPPE.

Yours sincerely,

Joanne M. Bell, PhD
Senior Director
CNS Medical Affairs
Forest Research Institute

Forest Research Institute
A Division of Forest Laboratories, Inc.

Fax: 201-427-8100
Direct Line: 201-427-8353

December 28, 2004

FILE - VIA E-MAIL

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1429-FC

Dear Dr. McClellan:

Forest Laboratories appreciates the opportunity to provide you with additional comments following publication of the final rule implementing Section 611 of the Medicare Modernization Act (MMA) – the new initial preventive physical examination (IPPE).

In our previous comments, we recommended that CMS specify that an IPPE include a review of a beneficiary's mental status, cognitive function, and behavioral changes, three areas that are critical to the assessment of a beneficiary's risk for dementia and Alzheimer's disease. CMS declined to do so, primarily because the U.S. Preventive Services Task Force has found "insufficient evidence to recommend for or against screening for dementia with standardized instruments in asymptomatic persons." 69 Fed. Reg. 66284 (November 15, 2004). However, the preamble does go on to state that based on USPSTF guidelines, clinicians should remain alert for possible signs of declining mental function. While we are pleased that CMS recognizes the importance of staying alert to signs of declining mental status, we are concerned that the language of the preamble somewhat downplays the importance of detecting mental status changes in the elderly and misses the opportunity to provide physicians with clear guidance as to how the "required" elements of the IPPE can be used to identify beneficiaries "at risk" of developing dementias and Alzheimer's disease.

Confusion is a common problem in persons over 65 years of age. According to medical experts, four to five million Americans are diagnosed with some cognitive deficit, and the prevalence rates are increasing as the population ages. Decline in mental status and cognitive function can take many forms. In older persons, confusion can be a symptom

of delirium or dementia, although it can also be associated with mental illness, including depression. As we previously noted, studies show that individuals characterized as being cognitively impaired but not meeting clinical criteria for dementia or Alzheimer's disease have a high risk of progressing to dementia or Alzheimer's disease.[1] Both delirium and dementia have a wide variety of potentially reversible causes, but timely identification and intercession is needed to offset permanent dysfunction. Alzheimer's disease is a progressive degenerative disease characterized by memory problems that eventually lead to severe cognitive and functional impairment. Though there is no cure, treatment is available to help alleviate symptoms and slow the progression of the disease.

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