



March 1, 2010

Charlene M. Frizzera
Acting Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue
Washington, DC 20201

Dear Acting Administrator Frizzera:

On behalf of the 130,000 members of the American Society for Clinical Pathology (ASCP), I am writing to urge the Centers for Medicare and Medicaid Services (CMS) to fix several unintended flaws in the anti-markup rule on diagnostic services when CMS releases its 2011 Physician Fee Schedule (PFS) Proposed Rule later this year. The flaws with the current anti-markup rule are being aggressively exploited and the costs are being passed on to Medicare beneficiaries and taxpayers.

ASCP strongly supports CMS' efforts to address abusive billing arrangements in order to prevent clinical providers from profiting on their patient referrals for anatomic pathology and clinical laboratory services. Ever since CMS modified its anti-markup rule on diagnostic tests as part of its 2004 PFS Final Rule, non-pathologist physicians have been increasingly using a variety of schemes, such as "pod labs," in-office pathology labs and other contractual joint ventures, to capture the reimbursement intended for the performance of the AP services they order.

Abusive billing practices, such as markups, fee splitting and kickbacks, distort rational medical decisions, foster overutilization of medical services, increase health care costs to patients and payers, increase the potential for harm to patients resulting from unnecessary testing and treatments, and undermine patient trust in the medical profession. Studies have consistently shown that referrals to entities in which the referring provider has a financial relationship encourage excessive use of services and increase health care costs. Patients most likely to be affected by self-referral arrangements are often uninsured and those covered by private payers that have not adopted safeguards similar to those designed to protect the Medicare program from abusive billing practices. These arrangements hit hardest those patients least able to afford it.

These concerns, and the increasingly pervasive nature of abusive joint ventures involving pathology services, led ASCP to focus on the issue of self-referral, markups, pod labs, and related arrangements. The Society has been a strong and vocal advocate for reforming the anti-markup rule and the Stark Law's In-Office Ancillary Services (IOAS) Exception to deter billing abuse.

As part of our lobbying efforts, ASCP launched its "**Stop Pod Labs Now**" campaign to raise awareness of the problems these ventures pose to patient care and pathology quality with our

members, patients, Congress and the CMS. ASCP's efforts were so "successful" that one company threatened to file a lawsuit against us if we did not end our advocacy campaign.

In addition to numerous meetings with congressional leaders, ASCP met on several occasions with senior officials at CMS to discuss regulatory solutions to deterring abusive billing of pathology services. On May 11, 2007, ASCP President John S. J. Brooks, MD, FASCP; noted health care attorney Jane Pine Wood; and ASCP staff met with Don Romano, Lisa Ohrin and their staff at the Division of Technical Payment Policy (DTPP) to discuss our concerns.

These efforts bore fruit, as after extensive lobbying by ASCP and others within the pathology community, CMS revised its anti-markup rule as part of its 2008 PFS Proposed Rule. Despite technical problems with the 2008 PFS Final Rule, it ultimately forced the closure of scores of "pod labs" that were used by clinicians to mark up the cost of pathology services. Unfortunately, technical problems with the rule led to its inadvertent watering down as part of the 2009 PFS Final Rule, and the subsequent reemergence of a number of arrangements, such as in-office pathology labs, that have been established to profit on pathology services.

ASCP has also reached out to our colleagues at the American Clinical Laboratory Association, the College of American Pathologists, and several independent laboratories to establish the IOAS Exception Coalition to pursue the removal of AP services from the list of services excluded from the Stark prohibitions on self-referral. As part of the coalition's activities, ASCP met with Troy Barsky, Rhonda Ford and DTPP staff on April 30, 2009, to reaffirm our interest in and support for establishing an effective anti-markup rule for diagnostic services in the 2010 PFS proposed rule. ASCP also met with MedPAC on July 16, 2009, to raise concern about these abusive billing practices and the need for reforming the Stark IOAS Exception.

When CMS reengineered its anti-markup rule on diagnostic tests in 2007, it did so for the express purpose of preventing abusive billing practices by physicians billing for pathology services they ordered on their patients but did not perform. Unfortunately, as CMS revised the anti-markup as part of the 2009 PFS Final Rule, it inadvertently exempted from oversight precisely those billing abuses it sought to prevent: the markup of pathology services by ordering physicians.

The 2009 PFS revision to the anti-markup rule built on the changes made as part of the 2008 PFS, which allowed for the markup of diagnostic tests only when they are performed by a physician who "shares a practice" with the billing physician (the ordering physician). The 2009 rule revision established a two-test approach to determine whether the physician performing the service "shares a practice" with the billing physician or group practice. The first test requires that the performing physician (either the physician performing the PC or supervising the TC) furnishes at least 75 percent of his or her services through the billing physician or group practice. Alternatively, the TC and/or PC may be marked up if the service is performed in the office of the billing physician. While the first of these two tests may help deter self-referral arrangements, the latter test is weak and ineffectual. This test can easily be satisfied by *any* physician who is part of the billing group practice.

Currently, the nation is experiencing a surge in the number of physician group practices establishing in-office pathology (histology) laboratories for the express purpose of capturing the reimbursement for the pathology service. *Laboratory Economics* reported in November 2009 that the number of gastroenterology in-office histology laboratories more than tripled between 2005 and 2009 while urology in-office histology laboratories more than doubled during this time. Interestingly, there has also been a corresponding increase in the utilization of pathology services, both in terms of the number of biopsies being performed per patient and the number of patients being biopsied.

One of the problems with these schemes is that the TC is often “supervised” by a physician who has little or no training or experience supervising (or performing) histology (the TC of the pathology service). *This is because neither the Clinical Laboratory Amendments of 1988 (CLIA) nor Medicare requires that the physician supervising the processing of the biopsied specimen have any training or experience in pathology.* This major oversight in CLIA essentially allows the highly skilled, near art form field of histopathology—the key step in taking a tissue sample and preparing it for diagnosis—to be equated with trivial in-office laboratory tests considered exempt under CLIA. As a pathologist who has supervised histology labs for over 25 years, I can tell you this is not only nonsense but potentially very dangerous. Given the often irreplaceable nature of AP specimens, and the highly complex multistep process of properly making a biopsy into a slide, the improper supervision of this process can potentially have dire consequences for patient care.

ASCP believes the most effective and appropriate means to deter abusive billing practices involving pathology services is to remove these medical services from the IOAS Exception of the Stark Self-Referral Law. By its very nature, pathology should not be included among the on the IOAS exceptions. Pathology services are complex medical procedures requiring significant time, skill and expertise to perform properly. These services cannot be performed during a patient visit—the driving rationale for including medical services or procedures among the IOAS exceptions.

To fix these flaws with the anti-markup rule, ASCP recommends that the anti-markup rule be revised to prohibit the use of independent contractors by referring physicians or group practices billing for the performance of the PC and TC of a pathology service. Additionally, the supervision requirement for the TC should be revamped to mandate that it be provided by a physician (preferably an anatomic pathologist) meeting the high complexity laboratory director requirements enumerated in CLIA. Moreover, the supervision must be provided *on site* during the performance of the TC. Otherwise, billing abuses will continue unchecked at the direct expense of patient care. Alternatively, CMS could delete the “second test” that allows the markup of diagnostic tests performed in a physician’s office. Most of the flaws in the anti-markup rule are traceable to this part of the two-test approach. Lastly, ASCP urges CMS to reinstate the purchased test rules to prohibit physicians from marking up tests purchased from outside suppliers.

The ASCP is a nonprofit medical specialty society whose members are board-certified pathologists, residents, clinical scientists, certified laboratory professionals, students and educators. ASCP is one of our nation’s largest medical specialty societies and is the world’s

largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

ASCP is committed to working with CMS to stop the proliferation of any schemes that enable physicians and group practices to profit from the self-referral of pathology services. The anti-markup rule is an important tool to prevent abusive Medicare billing practices. We look forward to meeting with you soon as part of the IOAS Coalition. Please do not hesitate to contact me or Matthew Schulze, ASCP's Senior Manager for Federal and State Affairs, at (202) 347-4450.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark H. Stoler', with a stylized flourish at the end.

Mark H. Stoler, MD, FASCP
President, American Society for Clinical Pathology

cc: Senator Max Baucus
Senator Chuck Grassley
Representative Henry Waxman
Representative Frank Pallone, Jr.
Representative Jackie Speier
Representative Parker Griffith
Kathleen Sebelius HHS
Daniel R. Levinson HHS OIG
Jonathan Blum, CMS CMM
Liz Richter, CMS CMM
Laurence Wilson CMS CCPG
Troy Barsky, CMS DTPP
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