Federal

CAP Secures OIG/CMS Rule To Forbid Laboratories From Donating EHRs - On Dec. 23, the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS) released their final rulings regarding electronic health record (EHR) donations under the anti-kickback statute safe harbor and Stark exception. The rules extend the safe harbor/exception until the end of 2021 but exclude “laboratory companies” (providers of anatomic and clinical laboratory services) from the types of entities that may donate EHR items and services, eliminating the abuses associated with these donations, and representing a significant victory for laboratories and pathologists. OIG and CMS also clarified the existing prohibition on any action that limits or restricts the use, compatibility or interoperability of donated items or service. The CAP has long been opposed to laboratories as donors of EHRs, calling attention to anti-competitive behavior and abuses associated with EHR donations sought by referring physicians from laboratories.

CMS Halts Plan to limit Pathology Payments to APC Rates, Payments for Other Key Services Reduced - On Nov. 27, the Centers for Medicare and Medicaid Services (CMS) released interim final rules for the 2014 Physician Fee Schedule (PFS) and Hospital Outpatient Prospective Payment System (HOPPS). On the eve of Thanksgiving Day - CAP staff were at the ready and analyzed the Medicare rule the moment CMS published it on the Federal Register. A few hours later that night, CAP sent a detailed action alert to members that thoroughly outlined changes in the codes and with the promise of deeper analysis in the days ahead. Updates continued, for example, in the College’s STATLINE, FAQ documents and a 90-minute webinar session on Dec. 4.

In light of strong opposition from CAP and others, CMS decided not to proceed with its plan to cap payments under the 2014 Physician Fee Schedule at Hospital Outpatient Ambulatory Payment Classification (APC) Rates. (CAP advocacy was successful in securing opposition to the proposal from 113 members of the House and 40 Senators.) However, CMS reduced payment for certain Anatomic Pathology (AP) codes and expanded bundling of payments for all clinical laboratory tests (other than molecular pathology tests) performed on hospital outpatients that are currently billed to the Clinical Laboratory fee Schedule (CLFS). Changes in payment are as follows:
• **Immunohistochemistry: 88342 (PC & TC)** - CMS rejected the CAP’s proposal and instead will require the use of two new G codes for this service, including G0461 to report one unit of service per specimen and G0462 to report each additional stain for Medicare use. The Centers for Medicare & Medicaid Services instituted new Medicare only G codes for reporting immunohistochemistry despite significant concerns and intense advocacy work by CAP and other medical societies. **Note:** The College of American Pathologists conferred with Medicare officials on January 6, 2014 to discuss concerns regarding this code. Accordingly, this code is under active reconsideration by CMS.

• **Enhanced Cytology Services: 88112 (PC & TC)** - The code, which had not been revalued in 10 years and was targeted for review due to its high volume, is now delivered by less resource intensive techniques since it was first valued.

• **In situ hybridization services: 88365, 88367, and 88368 (PC & TC)** - CMS deferred final action on the revaluation of these services for 2014, but changes are anticipated beginning in 2015. The code family has not been reviewed in nearly 10 years. Increased use since the 2004 establishment of the FISH codes has prompted CMS to repeatedly call for payment review. However, in early December, the National Correct Coding Initiative (NCCI) posted new claim edits aimed at restricting utilization of in situ hybridization and immunofluorescence services (88346-7), among other services identified by CMS for review. The CAP will be communicating with CMS to address their assumptions with the intent of clarifying the NCCI edits.

• **88305 TC** - In the 2013 Physician Fee Schedule rule, CMS requested additional data review by the AMA/Specialty Society Relative Value Scale Update Committee (RUC) to support 2013 revaluation of this service. Based on the input received, no further cuts in payment were taken for 2014.

• **Prostate biopsies** - In its decision, CMS established new G codes (G0416-G0419) which will apply to all prostate biopsies (regardless of surgical technique) when 10 or more specimens are reviewed. Increased scrutiny in the reporting of multiple prostate biopsy specimens led to this policy change. Prostate biopsies with fewer than 10 specimens should be billed using CPT code 88305.

• **Optical Endomicroscopy** - CMS declined to set payment for unique pathology services associated with optical endomicroscopy and suggested that pathologists can bill for this service utilizing existing codes when applicable.

• **Molecular Pathology** - CMS finalized a work RVU of 0.37 for HCPCS code G0452 molecular pathology procedure; physician interpretation and report. CMS also notes that: “The decision to pay for molecular pathology codes under the CLFS required the creation of a new code for the interpretation and reporting services by pathologists on the PFS. We continue to believe that the creation of HCPCS code G0452 was appropriate to describe medically necessary interpretation and written report of a molecular pathology test, above and beyond the report of laboratory results.”

• **Changes to Medicare’s Hospital Outpatient Prospective Payment System (HOPPS)** - Beginning Jan. 1, 2014, payment for all clinical diagnostic laboratory tests (other than molecular pathology tests) performed on hospital outpatients that are currently billed to the Clinical Lab Fee Schedule (CLFS) will be “bundled” into payment for primary hospital outpatient procedures. The expanded bundled payment would apply for services that are 1) provided on the same date of service as the primary
service and 2) ordered by the same practitioner who ordered the primary service. Further, CMS decided to bundle payment for certain “add-on” codes with the initial service.

- **Physician Quality Reporting System (PQRS)** - In its final rule, CMS did not accept the CAP’s three new pathology quality measures, but CMS has pledged to reconsider CAP’s three new measurers for inclusion in the 2015 measure set. However, CMS will allow pathologists to qualify for 2014 incentives by reporting on the existing five measures by either claims or registry. CMS is also finalizing several related proposals to the PQRS for 2014, CMS is aligning PQRS measures with the National Quality Strategy and meaningful use requirements, and transitioning away from process measures in favor of performance and outcome measures. These changes move the PQRS program in a direction that is less applicable to pathology. For this reason, the CAP is working with Congress on the SGR to create flexibility in the PQRS program and exempt pathologists from meaningful use requirements.

**CMS Finalizes 2014 PQRS Requirements for Medicare Bonuses, Penalties** - The Medicare program has finalized tougher criteria for earning Physician Quality Reporting System incentives in 2014, but pathologists will not face 2016 penalties when no quality measures apply to their practices. The Centers for Medicare & Medicaid Services finalized its rules on Nov. 27 for the 2014 PQRS and other quality programs in the Medicare physician fee schedule. In addition to other payment changes, CMS has outlined its criteria for earning bonuses and avoiding penalties stemming from PQRS reporting requirements. The 2014 PQRS incentive is equal to 0.5% of Medicare charges. An eligible professional participating in Medicare will be required to report on nine PQRS measures in 2014, an increase from a minimum of three measures in 2013, in order to earn a bonus. However, eligible professionals with fewer than nine measures applicable to their practice only need to report on all of the applicable measures (up to five for pathologists.) PQRS also includes a penalty for eligible physicians who do not meet reporting criteria. The College of American Pathologists had significant concerns over the agency’s cutting Medicare payments based on PQRS reporting activity when pathologists do not have enough applicable measures to report.

**CAP Co-Sponsors Summit to Address Pathology Workforce Issues** - In December, representatives of 24 national professional organizations, representing pathology and medical education, met in Washington, DC to develop a plan of action for how the pathology and laboratory medicine workforce of the future can best meet patient needs. The conference was sponsored by the College of American Pathologists (CAP), the American Society for Clinical Pathology (ASCP), the Association of Pathology Chairs (APC), and the United States & Canadian Academy of Pathology (USCAP). The conference focused on actions in three main areas: (1) re-assessing what every pathologist needs to know and identifying new ways to ensure that adequate numbers of pathologists acquire both general skills and sub-specialized expertise, especially in key emerging areas; (2) organizing pathology to attract and recruit highly-qualified medical and STEM (science, technology, engineering, and mathematics) students into pathology and laboratory professions; and (3) re-evaluating long-term training expectations and practice roles for all members of the laboratory workforce, in light of emerging technologies and evolving healthcare delivery models.

**Temporary SGR Patch Enacted** - Before adjourning for the year, lawmakers in Washington worked to stop deep cuts scheduled for 2014 under Medicare’s sustainable growth rate (SGR) formula. As part of an overarching budget agreement, the House had passed a three-month patch to avert the 24% cut scheduled to take effect in 2014. The patch was included as part of a House-Senate budget agreement. The budget deal then passed the Senate on Dec. 18. President Barack Obama signed the legislation that
includes the three-month fix. The temporary SGR patch would give Congress time to complete work on a permanent SGR repeal bill in 2014.

Contemplated Payment Reforms Ensure Flexibility for Pathologists - Members of Congress also made significant progress on drafting legislation to repeal and reform the current SGR Medicare payment update system permanently. On Dec. 5, the House Ways and Means Committee and Senate Finance Committee released legislation that repeals the SGR formula. The proposals are intended to remove the annual threat of across-the-board payment cuts and establish a new program to determine physician payment updates under the Medicare program. The new payment update program would combine current CMS incentive and pay-for-performance programs including Physician Quality Reporting System, Meaningful Use of Electronic Health Record technology and the Value Based Modifier to create a new value-based performance program (VBP). How a physician performs on the metrics for these programs would determine the payment update. The Finance and House Ways and Means Committees marked-up their respective proposals on Dec. 12. Ways and Means Chairman Dave Camp (R, Mich.) included in the House bill a provision that will help ensure pathologists have flexibility in meeting performance measures and activities under the new VBP program. The amendment had the support of the College of American Pathologists.

CAP calls on CMS to address billing policy for listing the date of service - The College of American Pathologists outlined in a Nov. 27 letter its concerns regarding billing policy for reporting the date of service of the professional component for laboratory tests on Medicare claims. In the absence of a national policy, some Medicare Administrative Contractors (MACs), which are responsible for processing claims, have developed new date of service guidelines while other contractors have left the decision to providers. The CAP letter recommended to CMS that it issue a national policy adhering to the long-standing industry practice that the date of service for the professional component (PC) be the same as the date that the technical component (TC) is performed. CAP also recommended that CMS prohibit MACs from imposing penalties or denying claims to providers that are working in good faith to implement changes to comply with the contractor policies. The common accepted practice has been to use the same date of the technical component of the service when billing for the professional component. Several MACs, such as WPS, NGS and Palmetto, recently required the date of service for the PC to be on the day the physician interprets the test, regardless of when the TC was provided. The CAP recommends to members that they check with their MAC to determine if the contractor also has adopted a new date of service policy.

State

CAP Request Reflected in Colorado Clean Claims Task Force Rule -The Colorado Clean Claims Task Force has issued a new draft editing and coding document that reflects the changes requested by the CAP on October 4. The CAP requested that coding edits adhere or conform to a 2012 state law that regulates billing for anatomic pathology (AP) services. The task force, in comments released in November, acknowledged its oversight of Colorado law, and stated that “the omission of modifier 90 from the proposed rule was an oversight, and we agree that it should be included.” Modifier 90 is a pass-through billing code now effectively banned for AP and subcellular/molecular pathology services under a 2012 direct billing law enacted in Colorado. The Task Force also stated that “the final rule will include a statement instructing that the professional component for AP and subcellular/molecular pathology can only be billed by the qualified healthcare professional who performs the interpretation”. Additionally, the rule will indicate that the technical component of the Pap test (including, cytopathology services for
cervical cancer screening Pap codes 88141-8175) cannot be billed by a health care provider when such services are performed by an outside laboratory.

**New Pennsylvania Law Tightens State Prohibitions on Inducements** - Legislation to substantially strengthen Pennsylvania's prohibition on clinical laboratories offering kickbacks, fee-splitting and rebates to ordering physicians has been enacted. In December, Pennsylvania Gov. Tom Corbett signed the bill, which had the support of the Pennsylvania Association of Pathologists (PAP). The PAP and College of American Pathologists successfully encouraged state lawmakers to amend the legislation in order to make sure that inducements for specimen referrals will be subject to condemnation and sanction under the law. The legislation, Senate Bill 1042, was initially introduced to broadly overhaul the state law regulating and licensing clinical laboratories. Additionally, Senate Bill 1042 extends state oversight authority to out-of-state laboratories that analyze specimens collected in Pennsylvania, but also allows the exemption of out-of-state laboratories from Pennsylvania inspection requirements—provided those laboratories have been licensed or accredited under the federal Clinical Laboratories Improvement Act (CLIA) and the home state, if applicable.