FDA Extends Filing Deadline for PET Radiopharmaceuticals

The Food and Drug Administration (FDA) has issued an extension to the December filing deadline for positron emission tomography (PET) radiopharmaceuticals.

On December 6, 2011, the FDA issued a six-month extension to the deadline by which all new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for PET drugs were to be filed. FDA has received requests to extend the application submission deadline from and on behalf of some PET drug producers trying to comply with the regulation and application submission requirements. The concern was expressed that if manufacturers are unable to submit their application by December 12, 2011, they will have to halt production of PET drugs for use in clinical care of patients. Further, although FDA does not anticipate any shortages of PET drugs after December 12, 2011, there is concern that sole producers in isolated areas may halt production if their application has not been submitted, and this could create a barrier to access in that particular area. Having considered these points, in addition to the fact that FDA has yet to issue the two instructive guidances for PET drug producers (Investigational New Drug Applications for PET Drugs and FDA Regulation of PET Drug Products, Questions and Answers) that are currently under development. FDA has decided to exercise enforcement discretion under the following circumstances until June 12, 2012.

For the next six months, until June 12, 2012, FDA does not intend to take enforcement action against a PET facility currently producing PET drugs for clinical use for a failure to submit a new drug application by December 12, 2011, provided that the facility complies with all other FDA requirements, including current good manufacturing practices (CGMPs). FDA will not exercise enforcement discretion after June 12, 2012. Therefore, if a facility wishes to continue to produce PET drugs for clinical use after June 12, 2012, they must have submitted an NDA or an ANDA by that date or be producing the drugs under an investigational new drug exemption (IND). PET producers who are unable to submit a NDA or an ANDA by June 12, 2012, or operate under an IND must find a new supplier who is in compliance. All PET producers must be operating under an approved NDA or ANDA, or effective IND, by December 12, 2015.

For additional information, please visit the FDA website:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm085783.htm

Please also visit the website for the Coalition for PET Drug Approval:
www.coalitionforpetdrugapproval.org
FDA To Hold Meeting on Generic Drug User Fees

On Thursday, December 8, the Food and Drug Administration (FDA) announced a public meeting to discuss recommendations proposed for enactment of a Generic Drug User Fee Act (GDUFA). This will give the FDA authorization to collect fees and use them in the review process for human generic drug applications, for associated Type II Active Pharmaceutical Ingredient Drug Master Files (DMFs) and for conducting associated inspections for fiscal years 2013-2017.

The meeting will be held on December 19 from 10 a.m. to 5 p.m. at the FDA White Oak Campus in Silver Spring, MD. Registration for this meeting is required and should have been received by December 12. For those unable to participate in-person, the meeting will be offered via webcast.

For more information, please click here.

SGR Fix Proposed Following Supercommittee Failure

After nearly three months of negotiations, the Joint Select Committee on Deficit Reduction, also known as the supercommittee, failed to reach an agreement on the deficit-reduction proposal, leaving in place a 27 percent cut in Medicare physician payments that will take effect on January 1, 2012. Under August’s debt limit increase law, the committee had until November 23 to vote on a proposal, but the panel had to have an agreement by midnight on November 21 to meet a requirement of 48 hours notice of any proposal.

Proposals that were submitted to repeal the SGR failed due to disagreement over fundamental principles for achieving deficit reduction. Partisan division over the mix of entitlement cuts and tax hikes kept the supercommittee from any agreement on a deficit-reduction package.

As a result, on December 9 House Republicans introduced H.R.3630, the Middle Class Tax Relief and Job Creation Act, which would pay for a two-year Medicare physician payment patch with a 1 percent increase. Offsets in the proposed legislation total $40.5 billion. Conversely, a two-year delay of a looming 27.4 percent cut to physician pay under the Sustainable Growth Rate formula, with a 1 percent increase, would cost an estimated $38.9 billion.

Specifically, the offsets are $13.4 billion over 10 years by recapturing the health-reform law’s insurance-exchange subsidies; $8 billion from cuts to the prevention and public health fund; $6.8 billion from outpatient evaluation and management (E/M) services; $10.6 billion in hospital bad debt; and $4.1 billion in disproportionate share hospital payments.

The SNM will keep you updated on any changes that may occur.

SNM Meets with CMS to Discuss Direct Supervision Issues

On November 21, the Society of Nuclear Medicine (SNM) met with the Centers for Medicare and Medicaid Services (CMS) to discuss the issue of “direct supervision” as it relates to the CMS Hospital Conditions of Participation (CoP) Nuclear Medicine Services 482.53(b)(1). In recent years some technologists have faced the problem of hospitals being cited by state inspectors in response to how the preparation of radiopharmaceuticals is supervised. SNM is drafting comments to CMS on this issue and will submit them before the December 23 deadline.

Legislation Introduced to Address 2012 Medicare Accreditation Requirements

On November 2, Rep. James Renacci (R-OH) introduced HR 3328, which would provide a six-month grace period for new Medicare imaging service suppliers to receive accreditation through an approved accrediting organization. The Medicare Improvements for Patients and Providers Act (MIPPA), which goes into effect on January 2, 2012, requires all suppliers billing under the Physician Fee Schedule for advanced diagnostic imaging (CT, MR, nuclear and PET) to be fully accredited in order to be reimbursed by CMS.

However, new facilities are unable to apply for accreditation until they have performed studies. The accreditation process then takes a minimum of 90 days. As a result, any new facility would not be reimbursed through Medicare for a minimum of four to six months.
In response, Rep. Renacci’s bill would establish a six-month grace period where new facilities would be paid while undergoing the accreditation process.

**SNM and ERF announce creation of Robert E. Henkin Government Relations Fellowship**

SNM and the Education and Research Foundation for SNM are pleased to announce the creation of the Robert E. Henkin Government Relations Fellowship. Nuclear medicine is a highly regulated profession, and it is essential for its leaders to have a first-hand understanding of regulatory challenges. This fellowship will provide gifted, highly motivated young nuclear and molecular imaging professionals with vital experience in the process of health policy development. Application deadline is Dec. 31.

For more information, please click [here](#).

**Update: CMS Releases Final ACO Rule**

On Thursday, October 20, the Centers for Medicare and Medicaid Services (CMS) released the final Medicare Shared Savings Program rule formalizing policies for voluntary accountable care organizations (ACOs), which differs significantly from the earlier proposed plan.

Under the originally proposed rule, CMS suggested two tracks for ACOs. Track 1 would have allowed an ACO to share the savings for the first two years and would have been required to transition in the third year to performance-based risk, sharing in both saving and losses. Track 2 would have required ACOs to assume risk for all three years of the program with more opportunity to share a higher percentage of the savings it generated.

Under the final rule, the two-track system remains but changes Track 1 to avoid downside risk. Inclusion of a one-sided risk model allows ACOs to participate in the Shared Savings Program without the threat of financial losses. The final rule requires that after the initial three-year participation agreement, if an ACO opts to remain in the Medicare Savings Program, it must participate in the Track 2 full-risk model described in the proposed rule.

In addition, CMS adopted recommendations to reduce the number of required quality measures from 65 to 33 and better align these measures with other quality reporting programs. Furthermore, CMS was cautioned that ACOs without a hospital would have difficulty reporting hospital-acquired conditions measures and that the majority of primary care physicians would be unable to adopt the burdensome “meaningful use” stage one requirements. Consequently in the final rule, CMS removed the hospital-acquired conditions composite measure and the requirement that at least 50 percent of an ACO’s primary care physicians must be “meaningful users” of electronic health records by the program’s second year. In its place, ACOs will be measured by the percentage of primary care providers who successfully qualify for an EHR incentive program payment.

If interested in participating in the program in 2012, ACOs can apply to enter the program on April 1 or July 1, 2012.

For more information on the final rule, please read the following full articles from the American Medical Association (AMA) and Arent Fox, LLP.

**SNM Draft Guideline Available for Public Comment**

The SNM Guidelines Committee continues to revise and update the practice guidelines and, in doing so, seeks member input in order to ensure we are developing the most accurate documents. The draft Practice Guideline for Brain Death Scintigraphy is now available for public input. The guideline will be available through the SNM website for review until Monday, January 9, 2012.

For information on providing comments and to view the draft guideline, please visit [http://interactive.snm.org/index.cfm?PageID=772#public-comment](http://interactive.snm.org/index.cfm?PageID=772#public-comment)
2012 Nuclear Medicine Coding Update Webinar

Each new year brings changes to coding and billing for nuclear medicine. Join Denise Merlino, MBA, CNMT, FSNMTS, CPC, as she recaps significant changes during the past year and discusses the common pitfalls and how to avoid them. The webinar will be held on Friday, December 16, 2011 at 11:30 am-1:00pm Central /12:30pm-2:00pm Eastern. SNM members, save 15%. Use code: SNMNUC12 when registering. For all information regarding the webinar, please click here.

CMS Issues Final Rules for HOPPS and MPFS

The Centers for Medicare & Medicaid Services (CMS) have issued the CY 2012 final rules for Hospital Outpatient Prospective Payment System (HOPPS) and the Medicare Physician Fee Schedule (MPFS).

The HOPPS final rule affects hospital outpatient and Ambulatory Surgical Center (ASC) payments for services paid under the outpatient prospective payment systems (OPPS). The final rule includes an update for hospitals in CY 2012 of 1.9 percent that incorporates requirements from the Affordable Care Act (ACA) legislation. As in years past, the ASC payment system is updated annually by the consumer price index. Based on this update, in combination with legislation from the ACA, CMS will apply a 1.6 percent update to ASC payments for CY 2012.

The MPFS final rule updates payment policies and rates for physicians and non-physician practitioners (NPPs) for services paid. More than 1 million providers of vital health services to Medicare beneficiaries – including physicians, limited license practitioners such as podiatrists, and NPPs such as nurse practitioners and physical therapists – are paid under the MPFS. CMS projects that total payments under the MPFS in CY 2012 will be approximately $80 billion.

Charts comparing the 2012 proposed rule to the final rule can be found on SNM’s website for both HOPPS and MPFS.
SNM Weighs In

SNM provides comments to government stakeholders on a multitude of issues. For more information, please visit the SNM Web site or contact the HPRA department directly.

- Comments to CMS regarding Hospital Conditions of Participation are due December 23, 2011.
- Comments to the Nuclear Regulatory Commission (NRC) on the Incorporation of Risk Management Concepts in Regulatory Programs are due January 6, 2012.
- Comments to CMS recommending improvements to the Coverage with Evidence Development (CED) process are due January 6, 2012.

Important Upcoming Events/Deadlines

- NRC Advisory Committee on Medical Uses of Isotopes Teleconference will be held on December 15, 2012, from 2:00 to 3:00 p.m. EST.

- On Monday, December 19, 2011, at 11 a.m. ET, FDA’s Small Business Assistance Program will present its webinar entitled CDER Small Business Webinar on PDUFA, which will be an overview of all aspects of the Prescription Drug User Fee Act (PDUFA), including waiver and reduction of user fees.

Contact hpra@snm.org to be notified by email of future newsletters.