Robert Califf Nominated as New FDA Commissioner

President Barack Obama has nominated Robert Califf, MD, to lead the Food and Drug Administration. Califf currently serves as FDA deputy commissioner, where he oversees the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health, among other offices. He began working for FDA in March, shortly before former Commissioner Margaret Hamburg announced her resignation. Califf is a leading cardiologist and former vice chancellor of clinical and translational research at Duke University. His appointment is subject to confirmation by the Senate.

VA Announces Milestones for ISBT 128 Labeling for Tissue Contracts

Quynh Vantu, Program Manager for the Veterans Health Administration Program Office of Pathology and Laboratory Medicine (PLMS) gave a recent update on the requirements for ISBT 128 labeling for tissue suppliers at the NATTAG meeting. PLMS was assigned oversight of tissue management processes for the VA’s 152 medical centers and over 200 outpatient clinics to improve systematic tracking and national supplier qualifications for tissue products.

The current Milestones for the contracting package with ISBT 128 labeling requirements for tissues are:

- Solicitation should be posted on October 5, 2015
- Technical evaluation of contracts will be the week of November 23rd.
- Tentative contract award date – February 12, 2016
- Vendor will have one year from contract award to comply with ISBT 128 requirements.
Members are reminded that Cornea-Trax is fully compliant with all ISBT 128 requirements and has been available for purchase since August. EBAA members enjoy at-cost pricing, which can save you thousands of dollars. Contact John Kling at JKling@digi-trax.com for more information.

**OIG Releases Questionable Billing for Medicare Ophthalmology Services Report**

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) released a report, *Questionable Billing for Medicare Ophthalmology Services*, which studied “questionable” Medicare billing practices by ophthalmologists. The study examined 34 million paid claims for ophthalmology services in 2012, and identified providers with unusually high billing for procedures that screen for, diagnose, evaluate, or treat wet age-related macular degeneration (AMD) or complicated cataracts.

The report found in 2012, four percent of providers billing Medicare for ophthalmology services demonstrated at least one of nine measures of questionable billing that OIG evaluated. Medicare paid these 1,726 providers $768 million for ophthalmology services in 2012, $171 million of which was for services associated with the measures where these providers demonstrated questionable billing. The measures of questionable billing were grouped into four categories: procedures to treat wet AMD, complex cataract surgeries, tests to diagnose wet AMD, and ophthalmology claims using modifiers. The report also found that Medicare paid $2 million for ophthalmology services to 821 providers that were not listed as eyecare specialists in the CMS databases. The report identified seven metropolitan areas where the percentage of Medicare payments associated with the measures was at least twice as high as it was nationally.

Based on the findings of the report, OIG recommends that CMS increase monitoring of billing for ophthalmology services, including using measures of questionable billing similar to those used in this study, and review and take appropriate action regarding providers with questionable billing identified in this study. CMS sent a response to OIG, stating that they agree with these two recommendations and will review the options for how to implement them effectively. For more information, view the full report.

**West Nile Virus Season Is Advancing**

According to the Centers for Disease Control and Prevention, 877 human cases of West Nile Virus (WNV) infection had been reported as of Sept. 22. Of these, 538 (61%) were classified as neuroinvasive disease (such as meningitis or encephalitis) and 339 (39%) were classified as non-neuroinvasive disease. Cases have been documented in 47 states and the District of Columbia, including 43 human cases that resulted in death.
Eye bankers are reminded that WNV is considered a relevant communicable disease by the FDA and potential donors should be considered ineligible if they have clinical evidence of WNV infection. According to the FDA Final Guidance, HCT/P Donor Eligibility (8-8-07): Persons who have had a medical diagnosis or suspicion of WNV infection (based on symptoms and/or laboratory results, or confirmed WNV viremia) you should defer for 120 days following diagnosis or onset of illness, whichever is later.

Recall of Sterile Compounded Products by US Compounding, Inc.

US Compounding, Inc. is voluntarily recalling all lots of sterile products aseptically compounded and packaged by USC and that remain within expiry due to FDA concern over a lack of sterility assurance. The sterile products were distributed nationwide to patients, providers, hospitals, or clinics between March 14, 2015 and September 9, 2015.

The recall does not pertain to any non-sterile compounded medications prepared by USC. Providers who received sterile compounded products from USC between March 14, 2015 and September 9, 2015, and that remain within expiry, to take the following actions:

- Discontinue use of the products;
- Quarantine any unused product until further instructions are received on how to return the product; and
- Contact USC at 800-718-3588 x254 or 501-327-1222 x254 from the hours of 8:30AM-5:00PM central time Monday-Friday, or e-mail at questions@uscompounding.com to discuss the return of any unused sterile compounded products.

Providers who have dispensed any sterile product distributed by USC to a patient(s) for use outside of the provider’s office should contact the patient(s) to whom product was dispensed and advise the patient(s) of this recall. Healthcare professionals are encouraged to report adverse events or side effects related to the use of these products to the FDA’s MedWatch Safety Information and Adverse Event Reporting Program. Complete and submit the report Online: www.fda.gov/MedWatch/report