



## The Focal Point: Advocacy & Legislative Update August 7, 2018

### CMS Releases OPPS and ASC Payment Systems for CY2019

The Centers for Medicare and Medicaid Services (CMS) released its [2019 Medicare Hospital Outpatient Department \(HOPD\) and ASC Payment proposed rule](#).

CMS has [released a fact sheet](#) which discusses the major provisions of the proposed rule.

### Pass-Through Maintained for Corneal Tissue

Most importantly for eye banks, the pass-through will be maintained for corneal tissue in CY2019:

*“Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; 42 CFR 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. **Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine** “*

### Proposed Updates to OPPS Payment Rates

CMS proposed increasing the OPPS rates by 1.25 percent in 2019. The agency arrived at its proposed rate increase through the following updates: a positive 2.8 percent market basket update, a negative 0.8 percentage point update for a productivity adjustment and a negative 0.75 percentage point adjustment for cuts under the ACA.

### Site-neutral payment proposal

Under the proposed rule, CMS would make payments for clinic visits site-neutral by reducing the payment rate for hospital outpatient clinic visits provided at off-campus provider-based departments to 40 percent of the OPPS rate. The clinic visit is the most common service billed under the OPPS, and CMS estimates the payment proposal would save the Medicare program and Medicare recipients a combined \$760 million in 2019. This change is projected to reduce OPPS payments by 1.2 percent, which would largely offset the 1.25 percent payment rate increase under the proposed rule.

### Proposed Updates to ASC Payment Rates

CMS proposes to update ASC payment using the hospital market basket index for 2019-2023, instead of the current consumer price index-urban (CPI-U). This change will help to promote site-neutrality between hospitals and ASCs and encourage the migration of services from the hospital setting to the lower cost ASC setting.

The change in update factor results in a 2 percent payment increase for ASCs meeting quality program requirements. The rate increase is a combination of the 2.8 percent inflation update based on the hospital market basket as well as a 0.8 percent reduction as mandated by the ACA.

CMS also proposes to modify its device intensive policy for the ASC. Procedures where the device cost exceeds a certain threshold of the total cost of the procedure are classified as device intensive and receive enhanced reimbursement. Currently, the threshold is 40 percent of the total cost, and CMS proposes to lower it to 30 percent to better accommodate the use of high cost devices in ASCs.

In the ASC Quality Reporting Program (ASCQR), CMS also proposes to eliminate ASC-11, Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery, because the costs associated with the collection of this measure outweighs the benefit of its continued use.

### **FDA Issues Draft Babesia Guidance for Blood Establishments**

The Food and Drug Administration (FDA) issued a draft guidance, [Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis](#), which classifies babesiosis as a relevant transfusion-transmitted infection under 21 CFR 630.3(h)(2). Draft recommendations include donor screening, donation testing, donor deferral, labeling and product management to reduce the risk of transfusion-transmitted babesiosis.

FDA recommends limiting donation testing to states with Babesia risk but requires both NAT and antibody testing year-round in those states. Blood establishments must test donors collected in Connecticut, Delaware, Maine, Maryland, Minnesota, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin and Washington, D.C. In the states where testing would be required, FDA would permit blood donor centers to discontinue asking donors about a history of babesiosis.

### **Medical Device User Fee Rates for Fiscal Year 2019**

The FDA has announced the fee rates and payment procedures for [medical device user fees for fiscal year \(FY\) 2019](#), which apply from October 1, 2018, through September 30, 2019.

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2017 (MDUFA IV), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration.

### **FDA FY2019 User Fee Table**

The FDA has [published the user fee amounts it will collect in FY2019](#) from the manufacturers of pharmaceuticals, generic drugs, biosimilars, medical devices and outsourcing facilities that produce compounded drugs.

### **eSubmitter Download**

FDA recently updated the eSubmitter software and the download instructions, user manual and quick guide.

[Download eSubmitter Software](#) (64-bit compatible only)

[Download User Manual](#) (Updated July 24, 2018)

[Download Quick Guide](#) (Updated July 24, 2018)

[Download eSubmitter FAQ](#) (Updated June 4, 2015)

### **Eye Bond Legislation to Fund Vision Research**

On July 18, bipartisan co-sponsors in the House introduced [The Faster Treatments and Cures for Eye Diseases Act](#), H.R. 6421. This legislation allows for the creation of “Eye Bonds” to finance packages of loans to projects at small labs, universities and other centers. They have the potential to mobilize as much as \$1 billion in research funding over four years, by incentivizing private investment in conjunction with public research dollars which would receive repayment priority. The National Eye Institute, part of the National Institutes of Health, would determine how many projects they would fund and at what amount, not to exceed \$250 million in any year.

The Eye Bonds are focused on translational research, meaning promising research “from bench to bedside” for all aspects of vision, including retinal diseases, cornea and optic nerve conditions, glaucoma, and eye injuries experienced by wounded veterans.

### **House Passes Bill to Repeal 2.3% Medical Device Tax**

The House passed H.R. 184, [the Protect Medical Innovation Act of 2018](#), by a vote of 283 to 132 to fully repeal the 2.3 percent excise tax on medical devices that was part of a funding source for the Affordable Care Act (ACA). It also delays the health insurance tax for two years, reverses the ACA's ban on using tax-preferred accounts for over-the-counter medicine, and tweaks health savings accounts (HSAs).

The bill will now head to the Senate. If it passes, President Trump is expected to sign it into law.

### **House Passes ASC Payment Transparency Act**

The House passed H.R. 6138, [the “Ambulatory Surgical Center \(ASC\) Payment Transparency Act of 2018,”](#) sponsored by Rep. Devin Nunes (R-CA) and Rep. John Larson (D-CT).

The bill requires CMS to specify the criteria it uses to exclude certain ASC-based surgical procedures from Medicare coverage. The bill also stipulates CMS can't exclude a procedure because of a general concern the procedure can only be reported using an unlisted surgical procedure code.

H.R. 6138 would add an ASC representative to the Advisory Panel on Hospital Outpatient Payment, thus ensuring that ASCs have a voice when CMS makes changes to payment policies. The law currently requires all members to be hospital- or health system-employed.

### **Robert Wilkie Sworn in As Veterans Affairs Secretary**

President Trump [swore in the fourth Secretary of Veterans Affairs in five years, Robert Wilkie](#). The VA has been without a chief executive for four months since the president fired Secretary David Shulkin.

Mr. Wilkie has worked for decades at the Pentagon and in the defense industry. He will lead the second-largest federal agency, with more than 360,000 employees and an annual budget of nearly \$200 billion. Wilkie will be tasked with leading an overhaul of the VA's private-sector care programs and overseeing a multibillion-dollar project to create a new electronic health record system.

### **Trump Administration Loosens Restrictions on Short-Term Health Plans**

The Trump [administration is clearing the way for insurers to sell cheaper, short-term health plans](#) as a bargain alternative for people struggling with high premiums. But the policies don't have to cover pre-existing medical conditions or provide benefits such as coverage of prescription drugs or maternity care.

Administration officials say the plans will last up to 12 months and can be renewed for up to three years, overturning an Obama administration directive that limited such plans to 90 days. The option is geared to people who want an individual health insurance policy but do not qualify for subsidies under the Affordable Care Act. Plans will carry a disclaimer that they do not meet the ACA's requirements and safeguards.

### **Latest Ebola Outbreak Spreads to DRC 'War Zone'**

Ten days after declaring an end to the Ebola outbreak in the western part of the Democratic Republic of the Congo (DRC), [the World Health Organization \(WHO\) confirmed a new outbreak in the eastern part of the country](#). This new outbreak in North Kivu province poses particular challenges as the region is a "war zone" with more than 100 active armed groups and thousands of displaced people.

WHO officials believe this outbreak's "signal event" was the death of a 65-year-old woman who had been admitted to the hospital in Mangina village. She was buried in an "unsafe burial by Ebola standards" and seven deaths occurred in her immediate family, all with similar symptoms. Thirteen cases were confirmed in North Kivu province and neighboring Ituri province, with another 30 "probable" cases registered, the DRC's health ministry said late Saturday.

Laboratory tests were positive for the Zaire strain of the Ebola virus disease, the deadliest strain, which has killed more than half the people who contract it in most outbreaks. While the highly effective "ring vaccination" strategy ended the outbreak in western DRC, conflicts between rival ethnic groups could hinder healthcare worker efforts, requiring armed military escorts for broader contact tracing.

### **UK Proposes a New System of Consent for Organ and Tissue Donation**

[Britain hopes to increase the number of organ donors by changing the rules of consent](#) and presuming that people have agreed to be donors unless they have specifically opted out. Legislation to introduce the new framework for organ and tissue donation will be debated in parliament later this year; if approved, the system would be expected to come into effect in spring 2020. Proposed exceptions to the presumed consent system include those aged under 18, individuals with limited mental capacity, and people who have not lived in England for at least 12 months prior to their death.