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in the news

Health Policy Monitor

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Health Reform and Related Health Policy News

In this Issue:

An executive summary of political, legal and regulatory issues that may impact your business, prepared by Polsinelli Health Care legal and Public Policy professionals.

Top News

Congress Approves Budget Deal with Short-Term 'Doc Fix'

By a vote of 64-36, the Senate passed a two-year budget agreement on December 18, 2013 that includes an extension of Medicare physician payment reimbursement rates through March 2014, as well as "extenders" for several other health programs set to expire on January 1, 2014. The Senate action followed the House of Representative's December 12, 2013 approval of the budget measure. President Obama has already stated that he will sign the agreement.

The three-month "doc fix," includes a 0.5 percent pay rate increase, and will allow House and Senate panels more time to process an overhaul of the Medicare physician payment system. The Congressional Budget Office said recently that physicians face a cut of 23.7 percent in Medicare reimbursement rates beginning Jan. 1, if current reimbursement rates are not extended by Congress.

Meanwhile, on December 12, 2013, the Senate Finance and House Ways and Means committees passed different versions of a Medicare physician pay overhaul proposal that the committees released in October. Both measures that cleared the two committees would permanently repeal Medicare's sustainable growth rate (SGR) formula, which each year calls for mandatory

cuts in physician payments that are routinely canceled by Congress with what is commonly referred to as a "doc fix." The proposal would replace the SGR formula with a new "value-based performance program" that attempts to better align Medicare physician payments with medical outcomes, moving away from the current fee-for-service system, which critics say rewards volume over quality. Additional coverage can be found here.

CMS "Two-Midnight" Rule delayed until March 31, 2014

In an effort to reduce Recovery Audit Contractor (RAC) denials of short inpatient stays, the Centers for Medicare & Medicaid Services (CMS) recently finalized a "Two-Midnight" rule in order to establish a bright-line test to determine which short stays are appropriate for inpatient reimbursement, and which stays are more appropriate for outpatient reimbursement. Under CMS' new standard, only hospital stays that physicians expect will last two midnights or longer will be presumed to be appropriate inpatient admissions. Importantly, CMS has stated that Medicare Area Contractors will generally not conduct post-payment patient status reviews for Medicare claims with dates of hospital admission on October 1, 2013 through March 21, 2014, three months longer than previously announced.

The rule for determining the appropriateness of inpatient admissions applies to surgical procedures, diagnostic tests, and other treatments (in addition to services designated as inpatient-only) provided in acute care inpatient hospital facilities, long term care hospitals, critical access hospitals and inpatient psychiatric facilities. Importantly, the benchmark applies regardless of a patient's severity of illness or the intensity of care required.

Several advocacy groups have expressed concerns that the rule will create various issues for providers, including how providers can bill medically necessary one-night inpatient stays and how hospitals will retrain physicians, modify health information technology systems, and change billing practices to comply with the rule. Advocacy groups continue to press CMS to modify or eliminate this rule before it starts getting enforced on March 21, 2014.

Individuals with Canceled Insurance Policies May Apply for Exemption From Fines and May be Eligible for Catastrophic Plan Options

According to guidance issued by CMS on December 19, 2103, people whose insurance policies were canceled and who determine their new options are "unaffordable" now may qualify for a "temporary" hardship exemption from the fines imposed against persons who are not covered as required by the Affordable Care Act (ACA). Most people who are not covered must pay a penalty, in the form of a "shared responsibility" payment, which starts at the greater of $95 or one percent of their income in 2014. The guidance also said that people whose 2013 policies were canceled because the policies do not meet the ACA's 2014 requirements for comprehensive benefits will be allowed to buy cheaper, catastrophic insurance policies. Typically, the law prohibits people age 30 or older from buying catastrophic policies through the ACA marketplace unless they qualify for a hardship exemption. The premiums for such catastrophic insurance plans are generally about 20 percent less than the premiums for other ACA marketplace plans. A copy of the CMS guidance can be found here.

HHS and Insurers Offer Extra Help and Extensions in Last-Minute Rush for January Coverage Under the ACA

Although the official deadline for obtaining ACA insurance coverage effective January 1, 2014 expired on December 23, 2013, HHS is continuing to work with people who were unable to complete the enrollment process due to technical difficulties with HealthCare.gov. Additionally, most health insurers have indicated that they would give consumers until Jan. 10 to pay for health coverage starting Jan. 1 as part of government-run exchanges under the federal healthcare law. California, Connecticut and Washington, as well as some other states, have indicated that they will follow slightly different deadlines. Under government rules, coverage cannot begin until people pay their first month's premium. Extending the payment deadline creates breathing room for the industry and for people who are eager for their insurance to begin, averting a holiday week in which tens of thousands of Americans might not know whether their coverage would start on time. Additional coverage can be found here.

Public Hospitals Push to Voluntarily Relinquish Tax-Exempt Status, Avoid ACA

Public hospitals are hoping to convince the Internal Revenue Service that they should be allowed to voluntarily give up their tax exemption, rather than be required to meet onerous "community benefit" standards set forth in the ACA. Section 9007 of the ACA revised Section 501(r) of the Internal Revenue Code regarding Federal tax-exempt status requirements for nonprofit hospitals. In order to ensure that hospitals are community benefit investments that are transparent, concrete, measurable, and responsive to a specific community need, the ACA requires hospitals to conduct a "community health needs assessment" every three years and adopt an "implementation strategy" regarding these goals. In the past, groups representing hospitals have pushed back against these standards, arguing that such criteria and the necessary paperwork are unduly burdensome and detract from their mission of providing quality care.

While generally public hospitals are viewed as government-owned entities that are already exempt from Federal taxation, public hospitals are required to meet the same requirements as other exempt hospitals under Section 501(c)(3) of the tax code, including the community benefit requirements. As such in a letter to the IRS obtained by Bloomberg BNA, the East Alabama Healthcare Authority has requested the IRS to adopt an administrative mechanism that would allow it and other public hospitals to avoid these requirements, especially the requirement that the hospitals perform a community health needs assessment at least once every three years because there is currently no mechanism in place for voluntarily withdrawing tax-exempt status.

In fact, it is the IRS' longstanding policy that once an organization is exempt, it is to remain exempt unless it terminates or liquidates.

CMS Announces New 2014 Participants in Medicare Shared Savings Program

On December 23, 2013, the Centers for Medicare & Medicaid Services announced that 123 new provider groups have been selected to participate in the Medicare Shared Savings Program (MSSP) in 2014 as accountable care organizations (ACOs). According to the CMS, the new ACOs include a diverse cross-section of health-care providers, including providers delivering care in underserved areas, who will provide care to approximately 1.5 million Medicare beneficiaries. The performance period for the newly

selected ACOs begins January 1, 2014. CMS will evaluate the ACOs performance using 33 quality measures including the patient and caregiver experience in connection with the medical care, care coordination and patient safety, appropriate use of preventive health services, and improved care for at-risk populations.

ACOs are intended to allow integrated networks of providers to share in the financial risks and rewards related to caring for and improving the health of a select group of patients. The health care reform law created the MSSP concept for this purpose. ACOs can seek to improve the quality and lower the cost of health care in many ways, such as disease management programs, care coordination and aligning financial incentives for hospitals and physicians. A copy of the CMS press release can be found here.

New OIG Report Questions Adequacy of the OCR's Oversight of HIPAA Security Rule

A report released December 4, 2013, by the United States Department of Health and Human Services ("HHS"), Office of Inspector General (the "OIG") raises concerns that the HHS Office of Civil Rights (the "OCR") itself is not doing enough to ensure the security of protected health information as required by the Health Insurance Portability and Accountability Act ("HIPAA"), and has failed to meet the requirements of the Health Information Technology for Economic and Clinical Health Act ("HITECH") mandating audits of covered entities. Although the report lauds the OCR for providing HIPAA covered entities with guidance regarding compliance with the HIPAA Security Rule, the report states that the OCR has not properly "assessed the risks, established priorities, or implemented controls for its HITECH requirements to provide for periodic audits of covered entities to ensure their compliance with [HIPAA] Security Rule requirements." According to the OIG, this failure constitutes a missed opportunity to encourage HIPAA covered entities to strengthen their security of electronic protected health information. Further, although the report recognizes that the OCR has established an investigation process for responding to reported violations of the HIPAA Security Rule requirements, the OIG cites the OCR for failing to follow such investigation procedures and sufficiently review audit documentation. As a result of these findings, the OIG recommends that the OCR more closely monitor whether HIPAA covered entities are complying with the HIPAA Security Rule by performing periodic audits of covered entities (as required by the HITECH Act).

In response to the Report, the OCR bemoaned that lack of funding has hampered its ability to comply with the OIG's recommendations, but nonetheless claims to have developed an audit protocol and performed pilot audits on covered entities. The OIG's very public rebuke of OCR regarding its failure to comply with its statutory mandates could create headaches for HIPAA covered entities that now risk having auditors implementing largely untested audit protocol on their facilities. While these audits may be tempered by the OCR's outcry regarding lack of funding, covered entities should get their proverbial house in order before the Feds come knocking. A link to the Report can be found here.

State News

Tennessee Cancer Clinic Owners Convicted in Misbranded Drugs Case

On December 12, 2013, owners of a Tennessee cancer clinic were convicted of charges related to introducing

misbranded drugs into interstate commerce (*United States v. Sen,* E.D. Tenn., No. 2:13-cr-56, *verdict* 12/12/13). Dr. Anindya Kumar Sen, his wife Patricia Posey Sen and their business, East Tennessee Cancer & Blood Center, were indicted on 38 felony charges alleging that they introduced misbranded drugs with the intent to defraud and mislead, alleging that they imported drugs contrary to law, alleging conspiracy on the drug charges, and alleging conspiracy to commit health-care fraud. Dr. Sen was the owner and managing physician of East Tennessee Cancer & Blood Center; his wife was the practice manager for the clinic. According to prosecutors, Patricia Sen began ordering drugs for the treatment of cancer from Clinical Care, a Canadian-based company that provides drugs obtained through foreign sources, in April 2009. Those drugs were not approved for use by the Food and Drug Administration (FDA), were not made at facilities registered with the FDA and their packaging contained foreign languages. As a result, they were considered "misbranded." The prosecution argued that such drugs are cheaper than approved drugs, which allows providers to increase profits from public benefit programs such as Medicare. Dr. Sen and Patricia Sen were convicted by a jury with the U.S. District Court for the Eastern District of Tennessee on certain charges included in a subsequent indictment. Sentencing is scheduled for April 30, 2014. According to the U.S. Attorney's Office for the Eastern District of Tennessee, the Sens both face up to 29 years in prison and maximum fines of $2.9 million. Additional coverage can be found here.

Seventh Circuit Affirms Challenge to Constitutionality of Wisconsin's Admitting Privileges Statute

Abortion providers in Wisconsin celebrated a decision issued by the U.S. Court of Appeals for the Seventh Circuit that affirmed an injunction pending trial that prohibits the state from enforcing a new law requiring doctors to have admitting privileges within 30 miles of their clinics (*Planned Parenthood of Wis., Inc. v. Van Hollen*, 7th Cir., No. 13-2726, 12/20/13). In the case, Planned Parenthood of Wisconsin Inc. and Milwaukee Women's Medical Services, filed this lawsuit challenging the constitutionality of Wis. Stat. § 940.15(5), which prohibits a doctor from performing abortions unless he or she has admitting privileges at a hospital no more than 30 miles from the clinic where the abortions are performed. The court, in a majority opinion written by Judge Richard A. Posner, acknowledged that a trial on the merits might cast the facts in a different light, but for now the record required the district court's grant of a preliminary injunction to be upheld. The court said the Wisconsin statute wasn't "unique." Six states have nearly identical laws, and five more have similar, though less stringent, requirements, it said. Judge Daniel A. Manion concurred in the judgment, but said in a separate opinion that he believed the state had shown a rational basis for the law. A similar challenge to Texas's admitting privileges law currently is pending in the U.S. Court of Appeals for the Fifth Circuit. A copy of the Seventh Circuit opinion is available here.

California Peer Review Panel Makeup Clarified by Court

On December 3, 2013, in *Chambi v. WMC-SA, Inc.*, Cal. Ct. App., No. G046922, the California Court of Appeals, Fourth District held that where feasible a physician peer review panel must include a member who practices in the specialty of the physician under review and that the hospital bears the burden of showing that it is not feasible to include such membership. This decision came about after a neurosurgeon challenged the composition of a physician peer review panel convened to investigate his alleged

substandard care, when the review panel did not include a neurosurgeon and the hospital's only reason for not include a specialist was that it was "too expensive."

Medicaid Expansion Plan In Pennsylvania Under Scrutiny

Pennsylvania advocates are challenging the penalties and premium costs in Gov. Tom Corbett's proposed Medicaid expansion plan. The advocates claim that tens of thousands of low-income Pennsylvanians would pay higher premiums in 2015 under the Governor's proposed Medicaid expansion than they would pay in 2014 for similar policies on the Affordable Care Act exchange. Some health-policy experts are concerned about the disparity, although coverage through Corbett's private-market alternative in most cases would still be cheaper, because there are virtually no out-of-pocket costs. Additional coverage is available here.

Delays In Medicaid Expansion Plan In Wisconsin Create Controversy

Approximately 83,000 adults without children in Wisconsin will have to wait at least three more months to receive Medicaid after state senators voted recently to delay their coverage while also pushing back the removal of about 72,000 other residents from the program. The Republican-controlled Senate passed the bill 18-12 along party lines, sending the measure to Gov. Scott Walker, who also signed the bill. On December 4, 2013, the Wisconsin Assembly voted 64-32 to respond to the enrollment problems surrounding the federal Affordable Care Act by delaying the termination of patients from Wisconsin Medicaid until April 1 instead of the January 1 deadline in current law. The bill being sent to Walker also delays by three months the end of separate state high-risk coverage known as the Health Insurance Risk-Sharing Plan. HIRSP had been scheduled to end on December 31st.

Regulatory News

Meaningful Use Stage 3 Delayed

On December 6, 2013, CMS announced that it will delay the start of Stage 3 of the meaningful use program for one year from 2016 to 2017. This means that Stage 2 of the meaningful use program has also been extended for one year. Eligible hospitals and eligible professionals that have received two years of meaningful use payments under Stage 1 will be required to meet the Stage 2 requirements in 2014. These providers will then also be required to meet the Stage 2 requirements in both 2015 and 2016. CMS has stated that the goal of this change is two-fold: first, to allow CMS and Office of the National Coordinator (ONC) to focus efforts on the successful implementation of the enhanced patient engagement, interoperability and health information exchange requirements in Stage 2; and second, to utilize data from Stage 2 participation to inform policy decisions for Stage 3. The delay of the start of Stage 3 will have no effect on the Medicare payment penalties that will begin in 2016 for those providers who have not successfully attested to being meaningful users of certified electronic health record technology.

OIG Report Announces Significant Recoveries and Program Exclusions During FY 2013

According to the OIG's Semiannual Report to Congress, the HHS OIG audits and investigations conducted in fiscal

year 2013 led to more than $5.8 billion in expected recoveries. The OIG's Semiannual Report to Congress also reported that HHS OIG excluded 3,214 individuals and organizations from participating in federal health-care programs, pursued 960 criminal actions against individuals and organizations engaged in illegal activity against federal health-care programs and brought 472 civil actions, including FCA cases and civil monetary penalty settlements. A copy of the report is available here.

OIG Issues Final Rule Amending Electronic Health Records Safe Harbor under the Anti-Kickback Statute

The Office of Inspector General issued a final rule amending the safe harbor regulation concerning electronic health records items and services, which defines certain conduct that is protected from liability under the Federal anti-kickback statute, section 1128B(b) of the Social Security Act. The Electronic Health Record ("EHR") Safe Harbor allows a hospital to provide non-monetary remuneration in the form of items and services necessary and used predominantly to create, maintain, transmit or receive EHRs by donating up to 85% of qualifying cost for a physician practice's purchase, implementation and maintenance of an EHR system meeting certain specified criteria. The amendments to the Safe Harbor in the OIG Final Rule include:

- Updating the provision under which electronic health records software is deemed interoperable;
- Removing the electronic prescribing capability requirement;
- Extending the sunset provision until December 31, 2021;
- Limiting the scope of protected donors to exclude laboratory companies; and
- Clarifying the condition that prohibits a donor from taking any action to limit or restrict the use, compatibility, or interoperability of the donated items or services.

A copy of the OIG's Final Rule can be found here.

OIG Report Says Hospitals Should Do More To Protect Against Fraud Linked to EHR Use

A report released December 10, 2013, by the OIG acknowledges that wide adoption of electronic health records ("EHR") might enable providers and suppliers to commit fraud more easily, and opines that hospitals with electronic health record systems may not be doing enough to prevent fraud related to the technology. The OIG questioned 864 hospitals that received EHR Medicare incentive payments as of March 2012 regarding whether or not they embed fraud safeguards within their systems. The safeguards are based on recommendations from RTI International, a nonprofit research group.

One of the OIG's main concerns stems from hospitals inappropriately using copy-paste features in their EHR. As stated in the report, "when doctors, nurses, or other clinicians copy-paste information but fail to update it or ensure accuracy, inaccurate information may enter the patient's medical record, and inappropriate charges may be billed to patients and third-party health care payers. Furthermore, inappropriate copy-pasting could facilitate attempts to inflate claims and duplicate or create fraudulent claims." According to the report, only 44 percent of hospitals' "audit log" systems record whether copy-paste was used to enter data, and the same percentage of hospitals reported that they can delete the contents of their

internal audit logs at will. It has been reported that CMS plans to issue guidelines on the proper use of copy-paste features within EHR systems.

DOJ Alleges Illegal Upcoding By National Physician Group Practice

The United States Department of Justice ("DOJ") has intervened in a *qui tam* Federal False Claims Act complaint targeting IPC The Hospitalist Co. Inc. ("IPC"), one of the largest providers of hospitalist services in the United States. IPC, which works in more than 1,300 facilities in 28 states, is accused of seeking payment for higher and more expensive levels of medical services than were actually performed – a practice commonly referred to as "upcoding." According to the DOJ, IPC encouraged its physicians to bill at the highest levels regardless of the level of service provided, trained physicians to use higher level codes and encouraged physicians with lower billing levels to "catch up" to their peers.

The lawsuit was initially brought by a hospitalist employee of IPC who discovered that IPC was improperly training its physicians to bill the highest Medicare codes available after TrailBlazer Health Enterprises, a Medicare contractor, required the physician to enroll in remedial billing courses in 2005. The lawsuit alleges IPC officials were aware of Trailblazer's suspicions about upcoding by IPC doctors.

CMS Manuals Updated to Reflect Jimmo Settlement Changes

In January of 2011, a law suit was filed on behalf of Glenda Jimmo and other Medicare beneficiaries alleging that the so called "improvement standard" caused a denial of beneficiary coverage for skilled nursing and therapy care if the beneficiary was not expected to improve from the treatment. In accordance with the Jimmo v. Sebelius Settlement Agreement, CMS has agreed to issue revised portions of relevant Medicare manuals, in order to clarify that when skilled nursing or therapy services are required in order to provide care that is reasonable and necessary (i) to improve a patient's current condition, (ii) to maintain the patient's current condition, or (iii) to prevent or slow further deterioration of the patient's condition, coverage cannot be denied based on the absence of potential for improvement or restoration. In other words, the settlement ended Medicare's practice of denying coverage to beneficiaries who have "plateaued," or were "stable," "chronic," or "not likely to improve." Portions of the revised manual provisions also included additional material on the role of appropriate documentation in facilitating accurate coverage determinations for claims involving skilled care. The revisions were published December 6, 2013, and took effect on January 7, 2014.

Florida Man Pleads Guilty to Role in $10.5M Medicare Fraud Scheme

An individual accused in a health-care fraud scheme involving about $10.5 million in false Medicare claims for therapy services never rendered pled guilty to a charge of conspiracy to commit health-care fraud. He faces up to 10 years in prison and a maximum fine of $250,000, or twice the amount of fraudulently obtained gains, whichever is greater. A copy of the FBI's press release can be found here.

Massachusetts Pharmacy Appears to be Nearing Settlement Over Tainted Injections

New England Compounding, the Massachusetts

pharmacy whose tainted steroid injections were blamed for a deadly outbreak of fungal meningitis, has agreed to establish a $100 million compensation fund pursuant to a tentative settlement for victims and their families, according to lawyers. Hundreds of victims have sued New England Compounding in state and federal courts. Nearly 14,000 people received the tainted injections last year with 64 deaths and about 700 others becoming sick. The outbreak raised concerns about the regulation of compounding pharmacies, which custom-mix large batches of medications. Additional coverage available here.

Additional Reading

- Politico: *Former Microsoft Exec Kurt DelBene Replaces Jeffrey Zients as Manager of ACA Website Overhaul*
- Modern Healthcare: *New Orleans Health Commissioner to Be National Coordinator for Health IT*

Federal Register

The FDA is seeking nominations from interested groups and individuals regarding specific bulk drug substances that may be used to compound drug products in accordance with Section 503B of the Federal Food, Drug, and Cosmetic Act, concerning outsourcing facilities, as well as information and nominations of drug products that present demonstrable difficulties for compounding. This section of the act prohibits outsourcing facilities from compounding using a bulk drug substance unless the substance is on the list. Sections 503A and 503B of the Act also prohibit compounding drugs that are on the list of drugs that present demonstrable difficulties for compounding. To identify candidates for these lists, interested groups and individuals may nominate specific bulk drug substances or categories of drug products. All information and nominations must be submitted by March 4, 2014. More information about nominating drug substances or categories of drug products can be found here.

During the month of December, the FDA released several draft guidance documents: "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act" can be found here and announces the FDA's intention with regard to enforcement of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to regulate entities that compound drugs, now that the FD&C Act has been amended by the Drug Quality and Security Act. This guidance, when finalized, will reflect the FDA's current thinking on the issues addressed by the guidance. Related to this draft guidance, the FDA announced the withdrawal of its guidance entitled, "Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act," which was issued in November 1998, and the withdrawal of CPG Section 460.200 of the Compliance Program Guidance (CPG) Manual entitled, "Pharmacy Compounding," which was issued in May 2002 because these guidance documents no longer reflect the FDA's current thinking on the issues they address.

Also related to Section 503B of the Federal Food, Drug, and Cosmetic Act, the FDA announced the release of draft guidance entitled "Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." This draft guidance addresses new provisions in the FD&C Act, as amended by the Drug Quality and Security Act (DQSA) and is intended to assist drug compounders that choose to register as outsourcing facilities in registering with FDA. The draft guidance provides information on how an outsourcing

facility should submit facility registration information electronically. The draft guidance can be found here.

The FDA released two draft guidance documents related to bioequivalence: (i) "Bioequivalence Recommendations for Paliperidone Palmitate," which provides specific recommendations on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for paliperidone palmitate extended-release injectable suspension, (ii) "Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA," which provides recommendations to applicants planning to include bioequivalence (BE) information in abbreviated new drug applications (ANDAs) and ANDA supplements. These two documents can be found here and here, respectively.

Finally, the FDA issued draft guidance for the industry "Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules." This guidance discusses FDA recommendations for the size, shape, and other physical attributes of generic tablets intended to be swallowed intact. The purpose of the guidance is to express the FDA's concern that generic drug characteristics are too varied compared to the originator drugs and the variation could affect patient outcomes. The draft guidance can be found here .

On December 11, 2013, the Centers for Medicare & Medicaid Services published an advance notice of proposed rulemaking (ANPRM), which can be accessed here, seeking public comment on specific practices for which civil money penalties (CMPs) may or may not be imposed on certain group and nongroup health plans for failure to comply with the Medicare Secondary Payer reporting requirements. Specific comments that are sought by CMS relate to the mechanisms and criteria that CMS employs in evaluating whether and how long there has been "noncompliance," when it would impose CMPs, methods of determining the dollar amount of CMPs that would be levied for each day that that a nongroup health plan is non-compliant, and methods for determining what constitutes "good faith effort(s)" taken by an entity to identify a Medicare beneficiary for purposes of the reporting requirements. Comments to the notice are due by February 10, 2014.

On December 17, 2013, the FDA issued a proposed rule to amend the 1994 proposed rule for over-the-counter (OTC) antiseptic drug products. The FDA proposed establishing conditions under which OTC consumer antiseptic products intended for use with water are generally recognized as safe and effective. In its proposed rule the FDA would require that all consumer antiseptic wash active ingredients have data that demonstrate a clinical benefit from the use of these consumer antiseptic wash products compared to non-antibacterial soap and water. A copy of the proposed rule is available here.

On December 18, 2013, the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) announced the extension of the pilot program for Parallel Review of Medical Products. The parallel review program is intended to reduce the time between FDA marketing approval and CMS national coverage determinations, thereby improving the quality of patient health care by facilitating earlier access to innovative medical products for Medicare beneficiaries. A copy of the notice is available here.

On December 23, 2013, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule which would establish national emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to ensure that they adequately plan

for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It would also ensure that these providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations. CMS is proposing the emergency preparedness requirements for 17 provider and supplier types, the specifics of which vary based on the provider type. A copy of the proposed rule can be found here.

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