



October 2015

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### **NEW DOL HOME CARE REGULATIONS EFFECTIVE OCTOBER 13, 2015, AFTER SUPREME COURT REFUSES STAY**

On October 6, 2015, the Supreme Court denied a request by the Home Care Association of America and related appellees to delay implementation of Department of Labor (DOL) regulations that require home care organizations to extend minimum wage and overtime protections to most home care workers. The regulations were issued by the DOL in 2013 but were invalidated by a pair of district court rulings in late 2014 and early 2015. The DOL appealed those rulings, and on August 21, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) reversed and [reinstated](#) the DOL regulations in the case of *Home Care Association of America et al. v. Weil*.

After the D.C. Circuit's decision, the appellees requested on September 24 a stay of mandate from the Supreme Court to delay implementation of the regulations while an appeal is filed with the Court. Chief Justice Roberts rejected that request, which paved the way for the DOL regulations, which took effect October 13, 2015. The DOL subsequently announced that it will not begin enforcement of the new regulations until November 12, 2015.

Robinson+Cole's Health Law Group will continue to monitor the Home Care Association of America's Supreme Court appeal and the impact of the DOL's regulations on the home care industry.

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### **OIG POLICY REMINDER CAUTIONS AGAINST EHR INFORMATION BLOCKING**

On October 6, 2015, the Office of Inspector General (OIG) issued an [alert](#) (Alert) regarding information blocking and the federal Anti-Kickback Statute (AKS) during the 2015 National Health IT Week. The Alert notifies providers of the OIG's concern that providers taking advantage of the AKS safe harbor for donating electronic health record (EHR) items or services (EHR Safe Harbor) are permitting improper information blocking by allowing donated EHR items or services to restrict compatibility with other EHR systems and/or inhibit the interoperability of such systems.

The AKS prohibits knowingly and willfully offering, paying, soliciting, or receiving any remuneration to induce or reward the referral or generation of business reimbursed by a federal health care program (that is, Medicare or Medicaid). Under the AKS, remuneration includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The Centers for Medicare & Medicaid Services (CMS) has enumerated safe harbors of permissible conduct under the AKS, including the EHR Safe Harbor, which protects arrangements involving the provision of interoperable EHR items or services, allowing providers, such as hospitals, to provide EHR items or services (in the form of software or information technology and training services) to physicians that could otherwise constitute illegal nonmonetary remuneration under the AKS, provided that the arrangement complies with certain requirements. Of relevance to the issue of information blocking, the EHR Safe Harbor mandates that the donor (or person acting on the donor's behalf) cannot take any action to restrict or limit the use, compatibility, or interoperability of the donated items or services with other EHR systems.

The Alert does not define information blocking, but it endorses the following definition used by the Office of the National Coordinator for Health Information Technology: "information blocking occurs when persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information." The Alert offers two examples of the types of actions that jeopardize compliance with the EHR Safe Harbor:

1. Arrangements in which the donor limits the use, communication, or interoperability of donated items or services by entering into an agreement with a recipient that prevents competitors from interfacing with the donated system
2. Arrangements in which technology vendors agree with donors to charge high interface fees to nonrecipient providers or suppliers or to competitors

The OIG takes the position that such actions raise serious concerns about the intent of the parties under the AKS; therefore, providers who intend to use the EHR Safe Harbor may be well served to pay close attention to the issue of information blocking.

Although the Alert does not discuss it, there is a parallel requirement under the Stark Law exception for the donation of EHR items or services that prohibits donors from taking any action to limit or restrict the use, compatibility, or interoperability of donated EHR items or services. The strict liability nature of the Stark Law provides additional incentive for providers to refrain from any type of information blocking.

Additionally, as of October 1, 2015, [Connecticut law](#) makes it an unfair trade practice for health care providers, including hospitals, to engage in "health information blocking." Health information blocking is defined to include interfering with the ability of patients, health care providers, or other authorized persons to access, exchange, or use EHRs or using an EHR to both (1) steer patient referrals to affiliated providers and (2) prevent or unreasonably interfere with patient referrals to health care providers who are not affiliated providers. Health information blocking does not, however, include legitimate referrals between providers participating in accountable care organizations or similar value-based collaborative care models. Consequently, health care providers in Connecticut have reason to be particularly vigilant in refraining from any practice that may result in information blocking.

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## **BIPARTISAN BILL PROPOSES TO EXPAND SUNSHINE ACT REPORTING REQUIREMENTS TO PHYSICIAN ASSISTANTS AND NURSES**

On October 7, 2015, Senators Charles Grassley and Richard Blumenthal introduced a bipartisan Senate bill ([Provider Payment Sunshine Act](#)) that extends the Physician Payments Sunshine Act's (Sunshine Act) reporting requirements to cover payments to physician assistants, nurse practitioners, and other advanced practice nurses. Currently, manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare or Medicaid are required to report payments or other transfers of value to doctors (of medicine and osteopathy), dentists, podiatrists, optometrists, and chiropractors, and such reports are made publicly available by the Centers for Medicare & Medicaid Services (CMS). Under the

Provider Payment Sunshine Act, covered manufacturers are required to similarly report all payments and transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives starting with reports due in 2017.

Manufacturers currently subject to the Sunshine Act who provide payments or other transfers of value to advanced practice registered nurses (APRNs) in Connecticut are likely also aware that Connecticut recently imposed state reporting requirements for such payments or transfers of value. Pursuant to [Public Act 14-12](#), as amended in 2015 by [Public Act 15-4](#), covered manufacturers are required to report payments or other transfers of value to Connecticut APRNs practicing independently of a physician to Connecticut's Department of Consumer Protection (DCP) on an annual basis, starting as of July 1, 2017. The Provider Payment Sunshine Act's proposed effective date, which requires reporting to commence in 2017, creates the possibility that manufacturers could be required to submit duplicative reports to CMS and DCP.

Robinson+Cole's Health Law Group will continue to monitor this proposed legislation and its potential impact on state laws as it navigates the legislative process.

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#### **INTERIM RULE ESTABLISHING ACO WAIVERS SET TO EXPIRE NOVEMBER 2, 2015; FINAL RULE EXPECTED IMMINENTLY**

Currently, accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP) are protected from potential liability under certain fraud and abuse laws by a set of five waivers (ACO Waivers). The respective ACO Waivers protect arrangements entered into by ACOs that are reasonably related to the purposes of the MSSP from enforcement under one or more of the Stark Law, the Anti-Kickback Statute, and the Civil Monetary Penalties Law's prohibitions on gainsharing and beneficiary inducement.

CMS issued an [interim final rule](#) implementing the ACO Waivers concurrently with its publication of the MSSP final rule on November 2, 2011. Because CMS established the ACO Waivers in an interim rule, CMS was required to issue a final rule by November 2, 2014. On October 17, 2014, however, [CMS extended the timeline](#) for publication of a final rule on ACO Waivers until November 2, 2015. Consequently, the interim ACO Waivers rule, currently relied upon by ACOs, will expire on November 2, 2015, or upon CMS publishing a final rule, whichever is earlier. Consequently, CMS is expected to issue a final rule on ACO Waivers imminently, and no later than November 2, 2015, that will supersede the interim rule.

Robinson+Cole's Health Law Group will closely monitor CMS's actions in the coming weeks and provide updates regarding publication of a final rule on ACO Waivers.

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If you have any questions, please contact a member of Robinson+Cole's [Health Law Group](#):

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