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Wolters Kluwer White Paper

2015's Top 10 Health Law Issues

Inside

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Executive Summary

In 2015, there were significant challenges made to the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148), also known as Obamacare, regarding the contraception coverage mandate, the increased health care coverage stemming from health insurance exchanges and the expansion of Medicaid, as well as the Congressional delay of some ACA provisions through the passage of fiscal year 2016 appropriations legislation. The sustainable growth rate (SGR), which has been sore spot for physicians for many years, was repealed in 2015 and replaced with a Medicare payment methodology that brings substantial changes to the physician payment process. Other noteworthy events in 2015 include: (1) a $237 million Stark law settlement against Tuomey Healthcare System in South Carolina; (2) additional guidance issued on the two-midnight rule; (3) a challenge to state Medicaid payment rates in Idaho that ended up before the Supreme Court; (4) the issuance of long-awaited food safety rules; and (5) the need to tighten up cybersecurity in the health care industry.

This White Paper, which takes a look back at the most important events affecting the areas of health care compliance and reimbursement, life sciences, and health reform, was compiled with the help of the Wolters Kluwer Legal & Regulatory Solutions U.S. Health Law editorial team—Sarah Baumann, Kathryn Beard, Jenny Burke, Mary Damitio, Sheila Lynch-Afryl, Melissa Mitchell, Anthony Nguyen, Michelle Oxman, Patricia Ruiz, and Bryant Storm.

Health Reform

#1 Contraception Coverage

One of the most contentious and heavily litigated topics arising from the ACA is the requirement that employer-sponsored health plans include, without cost-sharing, preventive services including all FDA-approved contraceptives. This topic received a fair amount of media attention in 2015 due to the issuance of new regulations governing the contraceptive mandate in July 2015 and the numerous legal challenges brought by religious nonprofits (see *2015's top 5 battles in the war against the ACA,* January 6, 2016).

***Zubik v Burwell* challenge.** Most notably, on November 6, 2015, the U.S. Supreme Court agreed to hear the challenges of seven religious nonprofit organizations seeking a decision to overturn the requirement that nonprofit organizations have to take action to opt out of the mandate to include contraception coverage as part of preventive health benefits. They also seek the benefits of exclusion that are granted to churches and other religious institutions (see *Supreme Court will hear 7 challenges to contraceptive mandate*, November 10, 2015). The case, which is referred to

Top 10 Health Law Issues of 2015	
Contraception Coverage	Two-Midnight Rule
Tax Subsidies, Health Insurance Exchanges, and *King v. Burwell*	Medicaid and the *Armstrong* Case
Medicaid Expansion	*Tuomey* and Physician Arrangements
Omnibus Spending Bill and the ACA	Food Safety: On the Road to Modernization
Sustainable Growth Rate and MACRA	Cybersecurity in Health Care

as *Zubik v. Burwell,* most likely will be scheduled for oral arguments in March 2016.

Freedom of religion. The accommodation to opt out of coverage itself, the organizations argue, is a substantial burden on their religious exercise. To request an accommodation, an organization originally was required to submit to its health insurer or third-party administrator (TPA) a self-certification form stating that (1) it opposes providing coverage for some or all contraceptive services required to be covered under the contraceptive mandate based on religious objections; (2) it is organized and operates as a nonprofit entity; and (3) it holds itself out as a religious organization (45 C.F.R. § 147.131(b)). HHS, however, amended the accommodation following the Supreme Court's order in *Wheaton College v. Burwell*, to simplify the opt-out procedure. Despite this simplification, religious organizations contend that the regulations substantially burden their religious exercise by continuing to require them to play a role in the facilitation of contraceptive use by their employees.

Seven federal appeals courts rejected their argument (2nd, 3rd, 5th, 6th, 7th, 10th, and D.C. Cir. courts), reasoning that the act of submitting an opt-out form relieves, rather than imposes, any substantial burden on religious exercise. In September, the 8th Circuit differed, finding the opt-out provision violates the Religious Freedom Restoration Act (see *Mandate, accommodation likely not least-restrictive means*, September 23, 2015).

What's coming in 2016? When the Supreme Court finally hears arguments in *Zubik*, it will be the second time in three years that the contraceptive mandate makes an appearance in the High Court. In June 2014, the Court held in *Burwell v. Hobby Lobby Stores, Inc.* that HHS regulations requiring employer-sponsored health plans to include FDA-approved contraceptives among the preventive services covered without cost sharing could not be applied to for-profit corporations with religious objections to some of the contraceptive methods (see *Closely-held 'corporate Christians' win crusade against contraceptive coverage*, July 2, 2014).

Final rule. In July 2015, in response to the Supreme Court's decision in *Hobby Lobby*, the Employment Benefits Security Administration (EBSA), CMS, and the Internal Revenue Service (IRS) maintained the accommodation to the contraceptive requirement available for eligible religious nonprofits and modified the definition of an "eligible organization," codified in Public Health Service Act (PHSA) Sec. *2713(a)*, as added by Section 1001(5) of the ACA (see *Closely-held corporations provided with contraception coverage accommodation in final regulations*, July 15, 2015).

Eligible organization. The Final rule (*80 FR 41318*, July 14, 2015) defined an "eligible organization" as an organization that opposes providing coverage for some or all of any contraceptive items or services required to be covered on account of religious objections and that: (1) is organized and operates as a nonprofit entity and holds itself out as a religious organization, or (2) is organized and operates as a closely held for-profit entity and the organization's highest governing body has adopted a resolution or similar action establishing that it objects to covering some or all of the contraceptive services on account of the owners' sincerely held religious beliefs.

Amended regulations *26 C.F.R. Sec. 54.9815-2713A*, *29 C.F.R. Sec. 2590.715-2713A*, and *45 C.F.R. Sec. 147.131* define a closely held for-profit entity as an entity that: (1) is not nonprofit, (2) has no publicly traded ownership interests, and (3) has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals.

#2 Tax Subsidies, Health Insurance Exchanges, and *King v. Burwell*

Making health insurance coverage available from health insurance exchanges with tax subsidies to pay for the premiums available for people meeting income requirements is a key part of the ACA. The debate over what Congress intended in providing those subsidies came to a head in 2015, and the outcome will have lasting implications on exchanges well into the future (see *Top five issues facing state exchanges in 2016*, December 9, 2015).

***King v. Burwell* decision.** Tax subsidies designed to help lower-income Americans buy health insurance

will remain available in all 50 states as a result of the Supreme Court's opinion in *King v. Burwell*, on June 25, 2015. The Court determined by a 6-to-3 vote what Congress intended when it passed the ACA in 2010. Opponents argued that subsidies issued by the IRS to cover a portion of the monthly premiums for health insurance policies purchased on HealthCare.Gov were illegal because the law's language indicated that only states that created their own health insurance exchanges could issue tax credits. The Court ruled, however, that the intentions of the law were clear, and the IRS could issue tax credits for states whether they created an exchange or used the federal exchange (see *SCOTUS rules in favor of ACA subsidies for federal Exchange enrollees*, July 1, 2015).

Had the ruling in *King v. Burwell* concluded that the subsidies were available only for individuals enrolled in health insurance plans through state-created exchanges, the result would have been to eliminate subsidies in 34 states and at least 6.4 million Americans likely would have lost insurance coverage. Given the way Congress wrote an interlocking law, the cascading effect of the loss of subsidies for so many probably would have collapsed the entire new system of purchasing health insurance over exchanges — a point that Chief Justice John Roberts embraced in foreseeing the potential for a "death spiral" for the ACA (see *Long live the King Responses to SCOTUS decision vary*, July 1, 2015).

State exchanges. The decision in *King* confirmed the availability of subsidies for residents in states that chose not to set up exchanges. The decision also provides assurance to those states considering transitioning away from their state exchange model that the federal exchange will continue to provide subsidies in the form of premium tax credits to their residents (see *The state of state exchanges post-King v. Burwell,* October 21, 2015, and *Don't know much about history: how the creation of the ACA informs King v. Burwell,* January 21, 2015). Although the issue of whether subsidies apply to the federal exchange has been resolved, exchanges continue to encounter complications in their creation, operation, and expansion.

Political shifts. While technological glitches and uncertainty over the availability of subsidies nationwide seem to have subsided, the political opposition to the ACA and the implementation of state exchanges continue in some states and on the federal level, particularly among Republicans, including members of Congress, presidential candidates, and governors. Even in states where the ACA has contributed to significant strides in health reform, such as in Kentucky, political shifts continue to threaten the future of the implementation of certain aspects of the ACA. In that light, states experiencing political shifts or perhaps simply caving into continuing political pressure could see the tide turn against their state exchange models.

Kentucky. Kentucky's exchange, Kynect, enrolled large numbers of its residents for health care coverage since its inception and reduced the uninsured rate to about 9 percent, according to a *Gallup Poll*. This drop was largely attributed to an aggressive media campaign, the usability of the digital platform, and the availability of a mobile app (see *The state of state exchanges post-King v. Burwell,* October 21, 2015; *Will the newly elected Kentucky governor send the ACA packing?*, November 10, 2015). Although many reports said this was unlikely to happen, the recently elected governor of Kentucky, Matt Bevin (R), *notified* the federal government on January 12, 2016, of his intention to dismantle the state exchange.

Failing exchange models. Many states are experiencing technical issues or are simply at an impasse with regard to the future of their exchanges. If any of these states ultimately choose to abandon their exchanges, they may determine, as Oregon and Hawaii did, that a complete transition to a pure federal model is not necessary or appropriate (see *State of Oregon signed away its immunity in Oracle deal,* November 24, 2015; *Aloha state exchange goes federal*, June 10, 2015). Both Oregon and Hawaii chose to implement a federally supported state exchange, *a model* in which states continue to perform marketplace functions but where the federal platform, Healthcare.gov, is relied on for enrollment.

Hybrids. Currently, 13 states have pure state-based exchanges while 27 rely solely on the federal exchange. Four states have created federally-supported marketplaces, while seven states have created state partnership marketplaces. In partnership marketplaces, the states administer in-person consumer assistance but rely on the federal exchange to administer all other marketplace functions. While hybrid models have been adopted by a small number of states, Oregon and Hawaii's adoption of these platforms when their state models failed is telling. If more states rule out pure state models based on the decision in *King,* hybrid models may be increasingly considered as they provide increased autonomy on the state level as compared to the full federal model. In an interview with Wolters Kluwer, *Layna Cook Rush*, Of Counsel at *Baker Donelson*'s Baton Rouge office, noted that because of "the expense [of] establishing a state run exchange, [and the] technical difficulties or enrollment issues[, states] may. . . consider a federal partnership so

that the state can still take advantage of the resources that it has already expended."

Federal and state exchange audits. In 2015, the HHS Office of Inspector General (OIG) released several reports that highlighted discrepancies that existed on the federal exchange. Specifically, the reports pointed out that (1) CMS did not properly account for costs on the marketplace, (2) CMS failed to properly oversee marketplace contractors, and (3) the internal controls on the marketplace needed improvement (see *Healthcare.gov due for maintenance: issues with eligibility determinations, data resolution*, August 12, 2015; *CMS oversight of marketplace contractors was bad for the bargain*, September 23, 2015; *CMS did not accurately account for federal marketplace costs*, September 30, 2015).

The OIG also found that insufficient controls in the Colorado health insurance exchange led to increased costs and the New York exchange failed to effectively verify enrollment eligibility (see *Insufficient internal controls, a costly mistake for Colorado*, April 22, 2015; *New York marketplace was not always effective in verifying enrollment eligibility*, September 30, 2015). In Maryland, a state audit revealed that the exchange did not appropriately monitor or record the use of funding received through grants (see *Maryland Health Connection failed to appropriately monitor funding use*, October 21, 2015). In 2016, it will be important to monitor how these states address such issues and if other audits or reviews of other state exchanges reveal similar findings.

What's coming in 2016? Some states relied on the federal exchange while awaiting the outcome of *King v. Burwell* in 2015, and others, like Arizona, adopted legislation foreclosing the idea of creating a state exchange regardless of the outcome in King (see *Arizona passes legislation, says no to state exchange*, April 22, 2015). Had the Court ruled that subsidies were only available for state exchanges, other state level actions may have been taken. As it stands, however, it is likely that many states that previously had considered building their own exchange will abandon that idea now that the Court has confirmed the availability of subsidies on the federal exchange.

#3 Medicaid Expansion

Thirty states and the District of Columbia have chosen to expand their Medicaid programs, either under the ACA or through a *section 1115 waiver*, helping to bring the uninsured rate among adults aged 18 to 64 ineligible for Medicare, traditional Medicaid, and the Children's Health Insurance Program (CHIP), down to 12.7 percent in 2015, compared to 22.3 percent in 2010 (see *CDC survey shows uninsured rate down to 9 percent of the population*, November 18, 2015). As more Americans obtain health insurance, hospitals have provided less uncompensated care and experienced a corresponding reduction in overall costs (see *Granite State expansion crushes uncompensated costs to gravel*, October 14, 2015; *Top 5 things to know about Medicaid expansion in 2015*, December 17, 2015).

> *Although "CMS can support expansion by working collaboratively with states," eventually "each state needs to come to its own conclusion and it is largely the compelling economics of expansion that has been encouraging more states to move forward."*
>
> – Cindy Mann, partner at Manatt, Phelps & Philips, LLP, and former CMS deputy administrator and director of the Center for Medicaid and CHIP Services

What's coming in 2016? Cindy Mann, partner at Manatt, Phelps & Philips, LLP, and former CMS deputy administrator and director of the Center for Medicaid and CHIP Services told Wolters Kluwer that "expansion isn't going to be driven by CMS encouragement." Although "CMS can support expansion by working collaboratively with states," eventually "each state needs to come to its own conclusion and it is largely the compelling economics of expansion that has been encouraging more states to move forward," she explained.

With their governors interested in the economic benefits of expansion, Utah, Wyoming, South Dakota, and Virginia will continue discussions in 2016. At this point, Mann expects most expansions will come through a waiver. "Inevitably, however, some states will wait until after the 2016 elections to see who occupies the White House in 2017," she added.

Here's what happened regarding Medicaid expansion in a few states:

- Although Pennsylvania received a section 1115 waiver for its Healthy Pennsylvania Plan in late 2014 (see *Medicaid expansion under Healthy Pennsylvania gets green light from CMS,* September 3, 2014), the state changed to a traditional expansion (i.e., expansion under the ACA rather than via a section 1115 waiver) in 2015 after Governor Tom Wolf's (D) inauguration (see *Not-So-Healthy Pennsylvania: Governor opts for traditional expansion,* February 11, 2015). Completion of the expansion was announced on July 27, 2015 (see *Pennsylvania's HealthChoices is up and running,* August 5, 2015).
- In Alaska, the state legislature refused to authorize expansion and included anti-expansion language in the state budget, so new governor, Bill Walker (I), used his executive powers to expand Medicaid (see *Alaska governor refuses to step away from Medicaid expansion*, July 22, 2015). In response, the legislature sought a preliminary injunction to stop the expansion (see *Last frontier of Medicaid expansion battle? Alaska legislature sues governor*, August 26, 2015), but a court denied the preliminary injunction, finding that the legislature could not prove irreparable harm and was unlikely to succeed on the merits. Further, the court reasoned that the legislature's use of the budget to forbid expansion violated the state constitution (see *Judge says Alaskan Medicaid expansion isn't irreparably harmful, won't cost 'one farthing'*, September 2, 2015).
- Montana expanded its Medicaid program using a section 1115 waiver approved by CMS in November 2015 after three years of bipartisan efforts. The Health and Livelihood Economic Partnership (HELP) Act (see *HELP is on the way to Big Sky Country,* May 6, 2015) authorizes Medicaid benefits beginning in January 2016. Upon CMS' approval, Governor Steve Bullock (D) informed eligible Montanans that they could immediately enroll (see *Montana has 70,000 problems but Medicaid expansion isn't one*, November 4, 2015).
- Florida has a Low-Income Pool (LIP) waiver from CMS that helps financially support safety net providers. Governor Rick Scott (R) included LIP funding in the state's proposed budget for 2015, but CMS said it would not renew it. Instead, CMS *encouraged* the state to expand Medicaid, rather than use supplemental funding (see *CMS tells Florida to drop the LIP, expand Medicaid*, April 22, 2015). Scott sued the Obama Administration (see *Florida governor stands firm against Medicaid expansion; Republican senate leans opposite direction*, May 6, 2015), alleging that CMS' response is no different from unconstitutionally conditioning all federal Medicaid funding upon expansion of program eligibility. Texas and Kansas filed a joint amicus brief in support of Florida (see *Texas and Kansas support Florida's fight against federal coercion*, May 6, 2015). CMS eventually agreed to partial funding of the program, but continued to offer suggestions as to other funding sources, including the expansion of Medicaid (see *Florida may get some funding for LIP*, May 27, 2015). Florida withdrew its claims, but the damage was done; the attorneys general of 10 states asked the House Ways and Means Committee to stop CMS from threatening funding and coercing Medicaid expansion (see *State AGs: stop CMS from 'trampling the rights of our sovereign states',* July 1, 2015).
- Arkansas, the first state to expand Medicaid using the "private option" with a section 1115 waiver demonstration project, considered changes to the program. Governor Asa Hutchinson (R) made plans to extend the project (see *Arkansas governor seeks expansion on private option*, January 28, 2015), and created an *Arkansas Healthcare Reform Task Force*, which commissioned a series of reports on how to improve the private option (see *Report goes hog wild with suggestions to improve Razorbacks' Medicaid*, October 14, 2015). Hutchinson incorporated some of the Task Force's suggestions into his plan for the program (see *Arkansas Medicaid redo list redone*, November 4, 2015). Changes include *restricting Medicaid expansion* through the use of an "asset test" and removing the opportunity for retroactive enrollment.
- While new Kentucky Governor Matt Bevin (R) made campaign promises to repeal both the state's exchange and its Medicaid expansion and terminate Kynect (see *Will the newly elected Kentucky governor send the ACA packing?*, November 10, 2015), he softened his stance on Medicaid after the election, ending his call for *full repeal* in favor of altering the expansion. A *large majority* of the state's citizens favored keeping expansion, and Bevin's inaugural address called to change the state's expansion to *follow the same model* as Indiana's section 1115 waiver. On January 12, 2016, Bevin *announced* the dismantling of the state exchange, Kynect, and restated his plans to reign in Medicaid expansion in the state.
- Louisiana's new governor, John Bel Edwards (D), who took office on January 11, 2016, and campaigned on the promise to expand Medicaid, hit the ground running by issuing an Executive Order on January 12, 2016, pledging to accept federal funding to expand, and set a July 1, 2016 deadline for the expansion (see *Louisiana governor follows through on expansion promise,* January 13, 2016). The state and the Louisiana Hospital Association agreed in 2015 on a financing tool that would pool hospital resources to pay the state's share of expansion costs (see *Louisiana starts to swing towards expansion as legislature raises the tempo*, June 3, 2015). Recent questions about the financing arrangement may slow Edwards' plans, (see *Not so fast, Louisiana: expansion funding called into question*, December 2, 2015). but *Mann* told Wolters Kluwer that she expects Edwards will succeed in implementing expansion traditionally under the ACA.

The last year for which the federal government will assume 100 percent of the cost of Medicaid expansion is 2016. The federal financial participation (FFP) will be 100 percent through the end of 2016, but beginning in 2017, the FFP will fall to 95 percent, 94 percent in 2018, 93 percent in 2019, and 90 percent thereafter under Soc. Sec. Act sec. *1905*(y)(1). At that point, states will have to contribute 10 percent of the costs. According to Mann, the state contribution costs will be "more immediate," for newer states, but none will be caught unawares. To pay for the state share, Mann said, "States are mostly planning to rely on either the savings achieved from expansion or provider (usually hospital) assessments—or both." She also noted, "Many states are pursuing delivery system reforms by reducing preventable hospitalizations or unnecessary emergency room use; savings achieved through those efforts also could be used to cover some or all of a state's expansion costs."

#4: Omnibus Spending Bill and the ACA

The Consolidated Appropriations Act, 2016 (*P.L. 114-113*), funding the federal government for fiscal year 2016, was signed on December 18, 2015, avoiding a government shutdown and delaying some of the ACA's most controversial provisions (see *Top 5 ACA-related legislation and final rules for 2015,* January 13, 2015; *Shutdown avoided, ACA taxes delayed,* December 18, 2015; *Changes to ACA requirements, COOL, cybersecurity, and more in Appropriations Act*, December 23, 2015). The legislation also suspended country-of-origin labeling (COOL) requirements for certain muscle cuts of meat and included the controversial Cybersecurity Information Sharing Act (CISA) with enhancements to cybersecurity in the health care industry, which are discussed later.

Cadillac tax. Section 101 of title I, division P of the law amended ACA sec. 9001 by delaying the imposition of the "Cadillac" tax two years, until January 1, 2020. The Cadillac tax is a 40 percent excise tax on employer-sponsored health insurance that exceeds a certain threshold and was included in the ACA as an attempt to reduce the overall cost of health care by discouraging employers from offering high-cost plans.

Annual fee for health insurance providers. Section 201 of title II, division P of the law amended ACA sec. 9010(j) by imposing a one-year moratorium during 2017 on the annual fee imposed on health insurance providers, which the IRS *began collecting* in 2014.

Medical device tax. Health Care and Education Reconciliation Act (HCERA) (*P.L. 111-152*) sec. 1405(a)(1) imposes a 2.3 percent tax on the sale of certain medical devices by manufacturers, producers, and importers. Section 174 of Division Q of the appropriations bill amended *26 U.S.C. §4191*, as added by HCERA sec. 1405(a)(1), by imposing a two-year moratorium on the medical device tax for sales in 2016 and 2017.

Menu labeling rules. In December 2014, the Food and Drug Administration (FDA) published a final rule (*79 FR 71156*) establishing menu nutritional labeling standards pursuant to Section 4205 of the ACA (see *Finally final: FDA releases ACA mandated menu labeling requirements*, December 3, 2014). The rules require a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items to provide nutritional information on menus and menu boards beginning on December 1, 2015. In July, the FDA extended (*80 FR 39675*) the compliance date one year, to December 1, 2016 (see *FDA says a longer wait is on the table for restaurant labeling*, July 15, 2015).

Division A title VII section 747 of the appropriations bill prohibits the use of funds to implement, administer, or enforce the food labeling final rule until the later of December 1, 2016, or one year after the HHS Secretary publishes Level 1 guidance with respect to nutritional labeling of standard menu items in restaurants and similar food establishments.

Risk corridors. Section 225 of the Consolidated Appropriations Act, 2016 prohibits fund transfers to the *reinsurance risk corridors program*, as required by sec. 1342(b)(1) of the ACA. In October 2015, HHS *noted* that insurers will pay risk corridors charges of approximately $362 million for the 2014 plan year despite having requested $2.87 billion. In the event of a shortfall for the 2016 plan year, "HHS will explore other sources of funding for risk corridors payments."

Health Care Reimbursement and Compliance

#5 Sustainable Growth Rate and MACRA

On April 16, 2015, President Obama signed the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (*P.L. 114-10*) into law, which included the repeal of the sustainable growth rate (SGR) and making significant changes to the Medicare physician payment methodology (see *Five things from 2015 that aren't old news for senior care,* December 21, 2015). Prior to its

repeal, the SGR limited Medicare physician reimbursement by requiring reductions to physician payments when spending targets were exceeded.

SGR's failure. The SGR was enacted in 1997 to account for inflationary growth in Medicare expenditures for physician services. Four years after the SGR was first implemented, the SGR resulted in a 4.4 percent reduction in physician payments. Congress took action passing legislation to temporarily correct the reduction, resulting in a 1.4 percent physician payment increase for the year. For 12 years following that first corrective action, Congress continued to pass legislation to correct the physician payment decreases. The legislative remedies became known as "doc fixes."

Remedy. Due to an awareness that the "doc fixes" were only a temporary solution to the problem, multiple attempts were made to repeal and replace the SGR (see *Reforming the broken Sustainable Growth Rate—why a temporary "doc fix" is not enough, and what might be*, April 15, 2014). Congress finally found a solution, which it incorporated in MACRA, and put an end to over a decade of patchwork legislation (see *Ding dong, the SGR is dead!*, April 15, 2015).

What's coming in 2016 and after? New regulations may be coming in 2016 with regard to this new payment methodology, and there will likely be commentary from physicians and other experts as the plan continues to unfold. MACRA increased physician payments by 0.5 percent for the period from July 1 through December 31, 2015, and will continue that increase for each calendar year (CY) from 2016 through 2019. For CYs 2020 through 2025, the increase will be set at 0.0 percent. Then, updates will be calculated using two different payment tracks: one based upon alternative payment models (APM), and another based upon other performance. The law incentivizes physicians to transition to an APM with a 0.75 percent increase in payment to physicians that qualify. Other physicians will receive a 0.25 percent increase (see *Who will care for Medicare? Seeking a source of sustainability*, October 23, 2015). MACRA also established a new system known as the Merit-Based Incentive Payment System (*MIPS*). Under MIPS, eligible professionals (EP) will be obligated to meet certain quality and electronic health record reporting requirements. MIPS was designed to consolidate certain aspects of a number of quality measurement and federal incentive programs, including the electronic health record (EHR) incentive program, into one efficient framework.

#6: Two-Midnight Rule

The two-midnight rule remained a hot topic in 2015 (see *Top 5 hot issues in Medicare litigation: Looking back at 2015*, December 28, 2015). Inpatient admissions qualify for Medicare Part A payment if a qualified practitioner admits a patient with the expectation that the hospital care will cross at least two midnights. If the care is expected not to last this long, the services generally are billed as outpatient (see *HHS follows the rules, releases two-midnight rate reduction methodology*, December 1, 2015).

The new OPPS rule amended the two-midnight rule to allow a treating physician or other practitioner to use his or her best judgment to make exceptions to the two-midnight requirement subject to medical review by a quality improvement organization rather than a recovery audit contractor.

Final rule. Prior to the November release of the 2016 Outpatient Prospective Payment System (OPPS) Final rule (*Final rule*, 80 FR 70298, November 13, 2015), CMS allowed exceptions to the two-midnight rules for specified procedures (see *OPPS payment update a net cut for many*, November 13, 2015). The new OPPS rule amended the two-midnight rule to allow a treating physician or other practitioner to use his or her best judgment to make exceptions to the two-midnight requirement subject to medical review by a quality improvement organization rather than a recovery audit contractor. CMS notes, however, that stays of less than 24 hours should rarely be considered inpatient stays. The Final rule became effective January 1, 2016.

Litigation. Prior to the issuance of the OPPS Final rule in November 2015, which governs the start of two-midnight rule enforcement and the beginning of a net reduction of 0.3 percent of payments for many hospitals, a district court ordered HHS to re-promulgate its Proposed rule establishing the two-midnight rule (*Proposed rule*, 78 FR 27486, May 10, 2014). The court reasoned that, by not disclosing all of its methodology, HHS improperly deprived hospitals of the opportunity to comment on HHS' rationale for the rate reduction. While HHS had the authority under Medicare law to make rate reduction adjustments to cover the costs of the two-midnight rule, the agency violated the Administrative Procedure Act (APA) *(5 U.S.C. § 706(2)(A))* by not providing the actuarial basis for its conclusion that the two-midnight rule would increase costs for Medicare by increasing the number of inpatient stays. While it would be too disruptive to vacate the rate reduction, the court allowed the reduction to stand but required HHS to reissue the rule and allow for meaningful comments and agency reconsideration on the basis for the rate change (*Shands Jacksonville Medical Center v. Burwell*, D.D.C., September 21, 2015; see *Court orders HHS to allow further comments on two-midnight rule rate adjustment*, September 22, 2015). CMS issued its Notice with comment period (*80 FR 75107*) on December 1, 2015 (see *HHS follows the rules, releases two-midnight rate reduction methodology*, December 1, 2015). Comments must be submitted by February 2, 2016.

#7: Medicaid and the *Armstrong* case

A Medicaid payment rate dispute wound up before the Supreme Court in 2015 (see *The top five decisions in 2015 Medicaid litigation*, January 8, 2016). In *Armstrong v. Exceptional Child Center,* Medicaid providers claimed, and state agency officials agreed, that Idaho's Medicaid payment rates violated Soc. Sec. Act sec. *1902*(a)(30)(A) because they did not cover the cost of providing services.

The Supreme Court decided that providers may not sue state Medicaid officials to enforce the standards of Soc. Sec. Act sec. *1902*(a)(30)(A) concerning the sufficiency of payment rates (see *High court reverses 9th Circuit: won't allow providers to bring private action to challenge Medicaid reimbursement*, March 31, 2015). The statute provides that the state Medicaid agency must "adopt methods and procedures [to] … assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." The Court rejected the Ninth Circuit's ruling that the Supremacy Clause of the United States Constitution may be the basis for such a challenge.

The Supreme Court held that Congress had implicitly prohibited private enforcement of paragraph (a)(30)(A). Neither the Supremacy Clause nor the Court's general equity powers could be used to circumvent Congressional intent. By granting HHS wide discretion to administer the Medicaid program and providing for HHS to withhold Medicaid funding from states that do not comply with requirements, Congress entrusted HHS with enforcement. Allowing private lawsuits was inconsistent with that grant of discretion. In addition, the language of the provision was too broad and vague to enforce.

What does this mean? The Supreme Court decision in *Armstrong v. Exceptional Child Center* did more than simply remove the Supremacy Clause as a basis for challenges to state Medicaid policies. By ruling that Congress had completely foreclosed any possibility of private lawsuits when it gave HHS the option to enforce Medicaid law by withdrawing funding, the Court erected a new barrier to standing to sue. Because HHS' ability to withhold funding applies generally to all federal Medicaid requirements, analysis of the statutory language for Congressional intent to benefit individuals like the plaintiffs would be completely unnecessary.

#8: *Tuomey* and Physician Compensation Arrangements

A big lesson for health care providers came out of a Fourth Circuit decision in 2015 (see *The top five False Claims Act cases of 2015*, December 30, 2015). In *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.* , decided on July 2, 2015, a hospital experienced just how harsh the Stark Law (*42 U.S.C. § 1395nn*) can be when coupled with the False Claims Act (FCA) after the Fourth Circuit affirmed a $237 million verdict against it for engaging in prohibited referrals through physician compensation agreements (see *Decade-long Tuomey saga comes to a close*, July 6, 2015; *2015 FCA Litigation Review: An Old Act With New Tricks*, August 11, 2015).

Tuomey Healthcare System, Inc. (Tuomey) is a rural, nonprofit hospital that entered into part-time employment agreements with 19 physicians that required them to perform outpatient procedures at the hospital in exchange for guaranteed base salaries. The agreements also provided for productivity and incentive bonuses and the hospital paid for many of the physicians' expenses, including malpractice insurance and employment taxes.

After two trials, a jury found that the hospital's agreements violated the Stark Law and that the hospital also violated the FCA when it submitted 21,730 false claims totaling $39 million to Medicare. The court trebled the damages, added a civil money penalty, and entered a judgment of $237 million against the hospital.

Verdict upheld. On appeal, the U.S. Court of Appeals for the Fourth Circuit upheld the verdict, and found that it was reasonable for the jury to conclude that the hospital violated Stark and the FCA when it paid physicians for referrals due to the nature of the agreements under which the physicians received increased compensation as they performed more surgeries at the hospital, which, in turn, resulted in more facility fees for the hospital.

In his concurrence in *Tuomey* decision, Judge James Wynn Jr. found that while the jury did not act irrationally when it determined that that the hospital violated the law, he nevertheless expressed concerns that the Stark Law coupled with FCA has become, "a booby trap rigged with strict liability and potentially ruinous exposure," even for providers with good intentions.

What happens now? Former HHS Inspector General Richard Kusserow warned hospital compliance professionals to be cautious when dealing with any physicians' arrangements, especially those that would require multiple legal consultants to be deemed acceptable. Even in the case in which hospitals rely on the advice of an attorney, as was in the case in *Tuomey*, Kusserow noted, that advice is not absolute protection from the relevant laws and penalties. Instead, Kusserow suggested using outside independent experts to continuously evaluate these types of arrangements and avoid overly complex dealings and those that only take into consideration fair market value (see *Lessons learned from the Tuomey case*, July 9, 2015).

Regarding the subsequent Department of Justice (DOJ) settlement with Tuomey, in which the health care system agreed to pay the government $72.4 million to resolve the $237 million judgment against it and be sold to Palmetto Health, a multi-district health care system in Columbia, South Carolina (see *Tuomey saga punctuated with DOJ settlement*, October 19, 2015), Kusserow reiterated the lessons to be learned from this case and stressed that hospital compliance professionals: (1) immediately investigate any questions raised about an arrangement; (2) thoroughly and effectively analyze the commercial reasonableness of such arrangements; and (3) avoid shopping for and disregarding particular legal and expert advice on this topic (see *Kusserow on Compliance: Top five tips for compliance professionals for 2015 and beyond*, January 13, 2016).

Life Sciences

#9 Food Safety: On the Road to Modernization

The FDA estimates that certain regulated processed foods are responsible for foodborne illnesses that cost the American public about $2.2 billion each year. In late 2015, the FDA issued a number of Final rules to implement seven Food Safety Modernization Act (FSMA) *(P.L. 111-353)* requirements relating to issues such as foodborne illness prevention in human or animal food, verification and accreditation of foreign food suppliers, food supply protections, and sanitary food transport (see *Top five 'food fights' in 2015*, December 18, 2015).

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Preventive controls rule. It took until September 2015 for the FDA to issue the preventive controls rule regarding food for human consumption (see *Food safety rules finally deemed well done (cook time: years)*, September 17, 2015). The *Final rule* (80 FR 55908, September 17, 2015) (*Preventive Controls rule*) followed several high profile illness outbreaks traced back to various food products in recent years. The Preventive Controls rule is one of many to be issued as a result of a protracted fight in the U.S. District Court for the Northern District of California that began in July 2012 between the FDA and the public consumer

group Center for Food Safety over the agency's failure to adhere to deadlines under the FSMA (see *FDA, food safety advocates settle rulemaking litigation*, February 21, 2014, and *Federal court orders the FDA to promulgate food safety regulations required by the Food Safety and Modernization Act of 2010*, April 24, 2013).

While litigation was ongoing, the FDA offered a proposal addressing preventive controls for human food in January 2013. The agency was ordered in February 2014 to have a Preventive Controls rule filed by August 2015 (as well as additional deadlines for the other six rules). As such, in September 2015, the FDA issued the Preventive Controls rule, which: (1) updates current good manufacturing practices (CGMP) for human food by modernizing practice requirements by clarifying the FDA's position that CGMPs address allergen cross-contact, and (2) revises an exemption from the requirements regarding specific activities associated with raw agricultural commodities. Food facilities are required to implement written food safety plans assessed by the FDA and, most notably, indicate steps to prevent or minimize potential problems.

Animal feed rule. Issued at the same time as the Preventive Controls rule, the *Final rule* (80 FR 56170, September 17, 2015) on animal feed safety (*Animal Feed rule*) is designed to ensure the safety of animals consuming animal feed and prevent the spread of foodborne illnesses in humans who handle animal feed (see *FDA finally finalizes animal food safety rule under FSMA*, September 17, 2015). Although not identical, the FDA's Animal Feed rule requirements are similar to the requirements of the Preventive Controls rule, requiring covered facilities to: (1) implement CGMP regulations, and (2) develop and implement preventive controls as part of a written Food Safety Plan. Under the Animal Feed rule, Food Safety Plan documents are required to be kept for at least two years.

Produce safety rule. To minimize contamination with produce that could cause serious adverse health consequences or death, the FDA proposed a new set of produce standards in January 2013. Adopted in November 2015, the *Final rule* (80 FR 74354, November 27, 2015) (Produce Safety rule) establishes science-based minimum standards for growing, harvesting, packing, and holding produce and applies to both international and domestic produce growers (see *FDA establishes farming standards to prevent contamination of produce*, November 27, 2015). The Produce Safety rule covers most types of produce (fruits and vegetables) including, among others, apples, lettuce, and spinach. Some produce is explicitly exempt from the new requirements, including an exhaustive list identified by the FDA as "produce that is rarely consumed raw," produce grown for personal or on-farm consumption, and produce that is not a "raw agricultural commodity" (meaning a fruit or vegetable in its raw or natural state).

Foreign supplier rule. The FDA also adopted final regulations in November 2015 (originally proposed in July 2013) governing the Foreign Supplier Verification Programs (FSVP) for importers of food for humans and animals to ensure that imported foods meet applicable U.S. standards for foods (see *Foreign Supplier Verification Programs for importers finalized,* November 27, 2015). The *Final rule* (80 FR 74226, November 27, 2015), effective January 26, 2016, addresses the safety of imported foods and is closely tied to the *Preventive Controls rule* and the *Produce Safety rule*. The FSVP rule requires importers to verify that food they import into the United States is produced in compliance with the hazard analysis and risk-based preventive controls and standards as outlined in *Section 103* of the FSMA, is not adulterated, and is not misbranded with respect to food allergen labeling.

Accreditation rule. Finally, a *Final rule* (80 FR 74570, November 27, 2015) originally proposed in July 2013 established a program for the accreditation of third-party certification bodies that will conduct food safety audits of foreign food entities and issue facility certifications (see *FDA establishes accreditation program for third-party certification bodies conducting food safety audits*, November 27, 2015). Although the FSVP does not require the use of accredited third-party auditors, the FDA anticipates that once the FDA accreditation system is in place, importers may increasingly rely on audits by accredited third parties.

COOL and Consolidated Appropriations Act, 2016. The Appropriations Act suspended the COOL statute (*7 U.S.C. §1638a*) requirements for muscle cuts of beef and pork, and ground beef and pork. The COOL statute assigns retailers an obligation to inform consumers of the country of origin of meats sold in their establishment. This obligation can be quite complicated if an animal is born, raised, and slaughtered in more than one country. A 2013 Final rule (*78 FR 31367*) requires retailers of "muscle cuts" of meat, i.e., covered meat other than ground meat, to list the countries of origin and production steps—born, raised or slaughtered—occurring in each country. Canada and Mexico asked the World Trade Organization (WTO) for permission to retaliate against the U.S. COOL labeling requirements by imposing billions of dollars in tariffs; the WTO found that mandatory COOL requirements

violated U.S. treaty obligations. The United States Department of Agriculture (USDA) *announced* the immediate cessation of enforcement of those COOL requirements. The agency said that it plans to amend the COOL regulations "as expeditiously as possible to reflect the repeal of the beef and pork provisions."

What is coming in 2016? As a result of these rules, food producers and distributors should expect a flurry of activity as the FDA plans to finalize the two remaining FSMA rules, specifically on protecting the American food supply and sanitary transportation of food, by the end of 2016.

Cybersecurity

#10 Cybersecurity in Health Care

Why the cause for concern? Hackers are increasingly targeting medical data, for a variety of reasons. Names, addresses, Social Security numbers, and insurance information are not only used for common fraud, but also can be used to purchase and sell drugs illegally and commit Medicare and Medicaid billing fraud. Hackers could potentially access medical devices in use in hospitals to enter the hospital's network and access patient data. Medical devices in use by patients could be manipulated to negatively affect the patient's health. Hackers may use patient medical data or data about the type of information accessed by employees to engage in phishing scams.

Litigation. Although patients who are the victims of data breaches have largely been unsuccessful in lawsuits filed against covered entities (CEs) and business associates (BAs) under the Health Insurance Portability and Accountability Act (HIPAA) *(P.L. 104-191)*, a Seventh Circuit Court of Appeals decision handed down in a credit hacking case may put entities maintaining medical data at greater risk of litigation. In *Remijas v. Neiman Marcus Group, LLC* (July 20, 2015, Wood, D.), the court held that consumer class action plaintiffs had standing to bring suit against a national retailer based on injuries associated with protecting themselves against identity theft. The court noted, "customers should not have to wait until hackers commit identity theft or credit-card fraud in order to give the class standing, because there is an 'objectively reasonable likelihood' that such an injury will occur."

Legislation. Congress and the President also took action on cybersecurity issues in health care through the Cybersecurity Information Sharing Act (CISA) enacted as part of the Consolidated Appropriations Act, 2016 (*P.L. 114-113*). In addition to making it easier for private companies to share personal information with the government in cases of cybersecurity threats, CISA requires the HHS Secretary to: report to Congress on the Department's preparedness to respond to cybersecu-

Notable Data Breaches of 2015

There were several notable data breaches in 2015, affecting millions of health records and individuals:

- Anthem, the second largest health insurer in the U.S., was the victim of a hacking incident that compromised the data of 78.8 million individuals, including birthdates, Social Security numbers, street and email addresses, and employment data (see *Anthem victim to possibly largest ever health care data breach,* February 5, 2015).
- Premera Blue Cross reported a breach of 11 million records in March 2015 (see *Premera offering identity theft protection for cyberattack victims*, March 18, 2015). Government officials tied both the Premera and Anthem attacks to Chinese espionage (see *Hacking incidents connected, Chinese hackers to blame*, June 9, 2015).
- Excellus Health Plan, Inc. reported a cybersecurity attack on a network server that affected 10 million records (see *Excellus BCBS reveals August 2015 security breach*, September 11, 2015).
- The University of California, Los Angeles Health was the victim of a cyberattack that potentially compromised the protected health information (PHI) of 4.5 million individuals (see *Patients advised on protecting identity in light of UCLA Health data breach*, August 24, 2015).
- Medical Informatics Engineering (*MIE*), a HIPAA business associate (BA), discovered that it was the victim of a data breach that compromised the data of certain clients utilizing electronic health records, personal health records, and patient portals. The data of 3.9 million people were exposed.
- CareFirst BlueCross BlueShield experienced an *attack* affecting 1.1 million individuals.

rity threats, create a Health Care Industry Cybersecurity Task Force, and work with the Department of Homeland Security to align security approaches across the health care industry (see *Changes to ACA requirements, COOL, cybersecurity, and more in Appropriations Act*, December 21, 2015).

What's coming in 2016? HIPAA CEs and BAs must remain vigilant in preventing data breaches and have a response plan in the event a breach occurs.

Audits. As of September 2015, the HHS Office for Civil Rights (*OCR*), tasked with enforcing the HIPAA Privacy, Security and Breach Notification rules, did not have a permanent audit process implemented as required by the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009 (ARRA) (*P.L. 111-5*), indicated by two reports by the OIG (see *OCR's oversight of privacy, breach notification obscured by incomplete documentation, tracking*, September 30, 2015). In response to the reports, the OCR noted that it plans to launch its Phase 2 audit process in early 2016.

Entities should document all actions so that they may respond quickly to an audit, if necessary. CEs and BAs should provide an organized response to audits by naming one person within the organization to serve as a point of contact, and be succinct in responses to avoid raising issues that are not the focus of the audit (see *OCR Phase 2 audits to focus on specific HIPAA rules*, July 17, 2015). Some professionals recommend using the OCR's audit program protocols as a guide for internal security and privacy risk analyses. CEs should upgrade agreements with BAs to ensure that they provide "satisfactory assurances" of compliance (see *2015 OCR HIPAA Audit: Getting ready for the 'deep' review*, April 28, 2015).

Encryption. Encryption of data, which essentially makes data appear meaningless without a key or other confidential process, is also important, although not explicitly required. Alessandra Swanson, Supervisory Equal Opportunity Specialist (SEOS) Team Leader for the OCR Midwest Regional Office, noted that encryption is "easy, generally inexpensive, and it's probably the best way to prevent a breach" (see *Is encryption the key to patient data security?*, July 8, 2015).

Two-factor authentication. The Office of the National Coordinator for Health Information Technology (ONC) reminded entities that two-factor authentication, which requires users to provide at least one additional form of identification beyond user name and password to gain access to ePHI, is a cost-effective way of ensuring that only authorized users access data (see *Is two-factor authentication part of your cybersecurity strategy? It should be*, December 9, 2015). Examples of additional identification include responses to security questions and asking the system to send randomly generated numbers to users' personal mobile devices.

Conclusion

The top issues addressed in this White Paper will continue to make headlines well into 2016. The 2016 presidential election will take center stage, and many of the ACA provisions will be heavily debated by candidates. The *Zubik* case brings yet another challenge to the ACA for the Supreme Court to hear, once again involving the contraception mandate. The new payment methodology for physicians will continue to play out, and further commentary from physicians is probable. In addition, the stage is set for additional guidance on issues such as (1) the *Armstrong* case and Medicaid payment rates, (2) the two-midnight rule, (3) physician compensation arrangements as in the *Tuomey* case, (4) food safety, and (5) ongoing cybersecurity threats for health care providers.