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Affordable Care Act regulatory issuances: 2014 in review

Inside

By Sheila Lynch-Afryl, JD, MA

In 2014, the federal government implemented a number of requirements of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148). During this time, more than 30 final rules implicating the ACA have been published; these regulatory issuances cover a broad spectrum, from the most talked about—such as the employer mandate—to standards for Health Insurance Exchanges, tax issues, various payment systems, and the establishment of the Basic Health Program. This White Paper provides a brief retrospective of these final rules.

Employer Mandate

Internal Revenue Code (IRC) section 4980H, as added by section 1513 of the ACA, constitutes the employer mandate. On February 12, 2014, the Internal Revenue Service (IRS) published a final rule (79 FR 8544, February 12, 2014) implementing the requirements of section 4980H (see *IRS issues final employer shared responsibility regulations along with significant new transition relief*, February 12, 2014).

Applicable large employer. Pursuant to new 26 C.F.R. sec. 54.4980H-2, beginning January 1, 2015, an employer's status as an applicable large employer for a calendar year is determined by taking the sum of the total number of full-time employees (including any seasonal workers) for each calendar month in the preceding calendar year and the total number of full-time equivalent employees (FTEs) (including any seasonal workers) for each calendar month in the preceding calendar year, and dividing by 12. If the result of this calculation is 50 or more, the employer is an applicable large employer for the current calendar year, unless an exception applies.

Assessable payment. Beginning January 1, 2015, under new 26 C.F.R. secs. 54.4980H-4 and -5, if an applicable large employer member fails to offer to its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan for any calendar month, and the applicable large employer member has received a certification that one or more employees have received a premium tax credit or cost-sharing reduction, the IRS will impose an assessable payment.

Similarly, if an applicable large employer member offers to its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan (including an offer of coverage to all but 5 percent or less of its full-time employees) and the applicable large employer member has received a certification that one or more employees have received a premium tax credit or cost-sharing reduction, then the IRS will impose an assessable payment equal to the product of the number of full-time employees for which the applicable large employer

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member has received a certification (see *Employer shared responsibility mandate—to pay or to play? That is the question,* June 25, 2014).

For purposes of the liability calculation, with respect to each calendar month, an applicable large employer member's number of full-time employees is reduced by 30.

Transition relief for 2015. The final rule, however, provided transition relief for 2015. For the 2015 calendar year, an employer may determine its status as an applicable large employer by determining whether it employed at least 50 full-time employees during any consecutive six-month period in 2014 instead of the entire calendar year.

The IRS also provided the following transitional relief for 2015:

1. delay of the employer responsibility provisions for employers with 50 to 99 full-time employees until 2016;
2. to avoid a payment for failing to offer health coverage, large employers must offer coverage to only 70 percent of their full-time employees in 2015 and 95 percent in 2016 and later;
3. employers with non-calendar year plans that were in effect as of December 27, 2012, generally do not need to comply with the employer responsibility provisions until the start of their plan years in 2015, rather than on January 1, 2015;
4. the policy that employers must offer coverage to their full-time employees' dependents will not apply in 2015 to employers that are taking steps to arrange for such coverage to begin in 2016; and
5. for the 2015 plan year, an employer may exclude 80, rather than 30, full-time employees from penalty calculations.

Steve Wojcik, vice-president of public policy at the National Business Group on Health, noted that "the rule recognizes the variations among employers, industries, and employment situations and takes a flexible, common sense approach." Seth Hanft, employee benefits and tax expert at law firm Porter Wright, warned, however, that the "transition rules are temporary and limited."

Contraceptive Mandate

The ACA requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide contraceptive coverage without cost sharing. Under 26 C.F.R. sec. 1.5000A-3, group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the otherwise applicable requirement to cover certain contraceptive services. The IRS, Employee Benefits Security Administration (EBSA), and HHS also provided an accommodation for group health plans established or maintained by certain nonprofit organizations with religious objections to contraception coverage.

In response to an interim order in connection with an application for an injunction pending appeal in *Wheaton College v Burwell*, 134 S. Ct. 2806 (2014), the IRS, EBSA, and HHS issued an interim final rule (79 FR 51092, August 27, 2014) providing that an eligible organization invoking the accommodation must either self-certify or provide notice to the HHS Secretary that it met the requirements of 26 C.F.R. sec. 54.9815-2713A(a) (see *Employees still protected, Feds provide birth control*, August 27, 2014).

Individual Mandate

Pursuant to section 5000A of the Internal Revenue Code, beginning January 1, 2014, for each month during the taxable year, a nonexempt individual must have minimum essential coverage or pay a shared responsibility payment. Minimum essential coverage means coverage under a government-sponsored program, an eligible employer-sponsored plan, a plan in the individual market, a grandfathered health plan, or other health benefits coverage.

In Final rule, 79 FR 70464, November 26, 2014, the IRS amended 26 C.F.R. sec. 1.5000A-2 to provide that the following are generally not considered government-sponsored minimum essential coverage: (1) Medicaid coverage for medically needy individuals; and (2) coverage authorized under *section 1115(a)* of the Social Security Act.

Further, pursuant to 26 C.F.R. sec. 1.5000A-3, an individual is an exempt individual for a month in which he or she lacks affordable coverage, i.e., his or her required contribution for minimum essential coverage exceeds the required contribution percentage of the individual's household income. For purposes of determining the affordability of coverage, the required contribution is reduced by any contributions made by an employer under a cafeteria plan that (1) may not be taken as a taxable benefit, (2) may be used to pay for minimum essential coverage, and (3) may be used only to pay for medical care. Under certain circumstances, amounts newly made available in the current plan year under a health reimbursement arrangement that is integrated with an eligible employer-sponsored plan are

taken into account in determining the employee's or related individual's required contribution (see *IRS rule to provide guidance on minimum essential coverage exemptions*, December 3, 2014).

Provider Enrollment

42 C.F.R. sec. 424.530 describes the reasons CMS may deny a provider's or supplier's request for enrollment in the Medicare program, including that the current owner, physician, or nonphysician practitioner has an existing overpayment. On December 5, 2014, pursuant to section 1866(j)(5) of the Social Security Act, as added by section 6401(a)(3) of the ACA, CMS provided, effective February 3, 2015, that it may deny enrollment because the enrolling provider, supplier, or owner was previously the owner of a provider or supplier that had a Medicare debt that existed when the latter's enrollment was voluntarily terminated, involuntarily terminated, or revoked and (1) the owner left the provider or supplier with the Medicare debt within one year before or after that provider or supplier's termination or revocation; (2) the debt has not been fully repaid; and (3) CMS determines that the uncollected debt poses an undue risk of fraud.

The enrolling provider, supplier, or owner can, however, avoid a denial under this provision if he or she satisfies the criteria described in 42 C.F.R. sec. 401.607 and agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt, or repays the debt in full.

Payment Systems

CMS made a number of changes to provider payment systems, including quality improvement programs, and issued regulations implementing the ACA-required prospective payment system (PPS) for federally qualified health centers (FQHCs).

FQHCs. Section 10501(i)(2) of the ACA established a PPS for FQHCs effective October 1, 2014. Under the final rule (79 FR 25436, May 2, 2014) implementing section 10501(i)(2), effective for cost reporting periods beginning on or after October 1, 2014, CMS will pay the costs of FQHC services under Medicare Part B based on prospectively set rates (see *Federally qualified health centers get prospective payment system*, May 7, 2014). For the first 15 months of the PPS, the estimated aggregate amount of PPS rates is 100 percent of the estimated amount of reasonable costs that would have occurred for that period if the PPS had not been implemented (see 42 C.F.R. sec. 405.2467).

Physician fee schedule. In the 2015 physician fee schedule final rule (79 FR 67547, November 13, 2014), CMS amended regulations relating to the value-based payment modifier, as required by ACA sec. 3007(2), for payments to physicians and groups of physicians. CMS also added 42 C.F.R. Part 403 Subpart K, which implements Soc. Sec. Act section 1115A, as added by ACA section 3021. Section 1115A enables CMS to test innovative payment and service delivery models to reduce program expenditures while preserving and/or enhancing the quality of care furnished to individuals under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP).

In addition, effective January 1, 2015, the anesthesia services furnished in conjunction with a screening colonoscopy are not subject to the Part B deductible.

For purposes of determining the affordability of coverage, the required contribution is reduced by any contributions made by an employer under a cafeteria plan that (1) may not be taken as a taxable benefit, (2) may be used to pay for minimum essential coverage, and (3) may be used only to pay for medical care.

CMPs recovered from SNFs. Section 6111 of the ACA, which amended Soc. Sec. Act sec. 1819(h)(2)(B)(ii), modified the imposition of civil money penalties (CMPs) against nursing facilities (NFs) and skilled nursing facilities (SNFs). It required the HHS Secretary to issue regulations, which "may provide" for the placement of the CMP funds in an escrow account during the informal dispute resolution and that a portion of the collected CMPs held in escrow be used to support activities that benefit residents.

Accordingly, in 2011, CMS promulgated new 42 C.F.R. sec. 488.433, which provided that 90 percent

of the collected CMP funds recovered against NFs and SNFs that are required to be held in escrow and that remain after a final administrative decision must be used entirely for activities that protect or improve the quality of care for facility residents. In the 2015 SNF PPS final rule, CMS modified section 488.433, effective October 1, 2014, to require a state to submit proposed activities to CMS and maintain an acceptable plan for the effective use of CMP funds. The amended regulation also provides for a new penalty for failing to spend CMP funds in accordance with section 488.433.

OPPS. In the calendar year (CY) 2015 hospital outpatient prospective payment system (OPPS) final rule, CMS provided that, pursuant to section 3401(i) of the ACA, the annual outpatient department fee schedule increase factor for 2015 is reduced by the multifactor productivity adjustment and an additional 0.2 percentage point (see 42 C.F.R. sec. 419.32) (see *CMS finalizes $5.1B OPPS payment increase, updates quality reporting programs*, November 12, 2014).

Further, pursuant to ACA sec. 6001(a)(3), a physician-owned hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010, unless the HHS Secretary grants an exception. A hospital applying for an exception may use data from external sources to estimate the required percentages of inpatient admissions under Medicaid only until such time as the Secretary determines that the Healthcare Cost Report Information System contains sufficiently complete inpatient Medicaid discharge data.

IPPS. In the fiscal year (FY) 2015 hospital inpatient prospective payment system (IPPS) final rule (79 FR 49854, August 22, 2014), CMS changed the scoring methodology for the Hospital-Acquired Condition Reduction Program, which implements ACA section 3008 by applying a 1 percent payment reduction for hospitals ranking in the top 25 percent for hospital-acquired conditions. Further, under the Hospital Readmissions Reduction Program, required by ACA section 3025, CMS expanded readmissions measures for FY 2017 and provided that the maximum payment adjustment for FY 2015 is 3 percent.

Other providers. CMS also updated the quality reporting programs for other providers, including inpatient psychiatric facilities, inpatient rehabilitation facilities, and hospices.

Food and Drugs

Section 9008 of the ACA, as amended by section 1404 of the Health Care Reconciliation and Education and Reconciliation Act of 2010 (HCERA) (P.L. 111-152), imposes an annual fee on covered entities engaged in the business of manufacturing or importing branded prescription drugs, effective December 31, 2010. Under the IRS's final rule, published July 28, 2014, a covered entity may provide information relevant to the determination of the fee by submitting Form 8947, "Report of Branded Prescription Drug Information." Each year, CMS, the Department of Defense, and the Department of Veterans Affairs provide data to the IRS on branded prescription drug sales that occurred during the sales year, and the IRS calculates a covered entity's total fee as described in 26 C.F.R. sec. 51.5.

Nutritional labeling. On December 1, 2014, the Food and Drug Administration (FDA) released two final rules concerning nutritional labeling for menus and vending machines (see *Finally final: FDA releases ACA mandated menu labeling requirements*, December 3, 2014; *Vending machine labeling requirements released with new menu labeling rule*, December 3, 2014).

In the menu nutritional labeling final rule (79 FR 71156, December 1, 2014), the FDA provided, pursuant to section 4205 of the ACA, that 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 must provide the following on menus and menu boards: (1) nutrition information for standard menu items; (2) a succinct statement concerning suggested daily caloric intake; and (3) a statement regarding the availability of additional written nutrition information. Calorie information for standard menu items that are self-service or on display must be listed on signs adjacent to the foods.

A covered establishment must have a reasonable basis for its nutrient declarations and must, upon request, provide to the FDA information substantiating nutrient values. A standard menu item offered for sale in a covered establishment will be deemed misbranded if its label or labeling does not comply with these requirements. Further, nutritional labeling in accordance with 21 C.F.R. sec. 101.9 must be provided upon request for any restaurant food or meal for which a nutrient content claim or a health claim is made, except that information on the nutrient amounts that are the basis for the claim may serve as the functional equivalent of complete nutrition information.

In addition, the FDA separately provided (79 FR 71259, December 1, 2014) that pursuant to ACA sec. 4205, vending machine operators who own or operate 20 or more vending machines are required to provide

calorie declarations for certain articles of food sold from vending machines. Vending machine operators do not have to declare calorie information for a food if a prospective purchaser can view certain calorie information on the front of the package, in the Nutrition Facts label on the food, or in a reproduction of the Nutrition Facts label on the food. For foods subject to the calorie declaration requirement, calorie declarations must be clear and conspicuous and placed prominently, and may be placed on a sign in, on, or adjacent to the vending machine, as long as the sign is in close proximity to the article of food or selection button.

Other Tax Issues

In 2014 the IRS has released a number of tax-related final rules implementing the ACA (see *Paying for the Affordable Care Act: 2014 Tax Year in Review*, December 30, 2014).

Charitable hospitals. In a December 31, 2014, final rule, the IRS implemented ACA sec. 9007, which imposed new requirements on charitable hospitals. Pursuant to section 9007, for taxable years beginning after December 29, 2015, a charitable hospital must, as a condition of its tax-exempt status, conduct a community needs assessment, establish a written financial assistance policy and a written policy concerning emergency medical care, and limit the amount charged for care it provides to any individual who is eligible for assistance under its financial assistance policy. A charitable hospital also may not engage in extraordinary collection actions against an individual to obtain payment for care before it has made reasonable efforts to determine whether the individual is eligible for assistance for the care under its financial assistance policy.

A charitable hospital that fails to comply with these requirements can have its 501(c)(3) status revoked. Emily McMahon, Deputy Assistant Secretary for Tax Policy at the U.S. Department of the Treasury, stated in a blog post that the purpose of the additional consumer protection requirements is to protect patients from "abusive collections practices." Indeed, "reports that some charitable hospitals have used aggressive debt collection practices, including allowing debt collectors to pursue collections in emergency rooms, have highlighted the need for clear rules to protect patients."

Tax credit for small employers. Small employers that provide insured health coverage to their employees are eligible for a tax credit pursuant to section 45R of the Internal Revenue Code, as added by section 1421 of the ACA. In June 2014, the IRS released a final rule (79 FR 36640, June 30, 2014) implementing section 1421 (see *Tax credit approved for small business and small tax-exempt business employers*, July 2, 2014).

Effective for taxable years beginning in or after 2014, to be an eligible small employer in a taxable year, an employer must have no more than 25 FTEs and must have in effect a qualifying arrangement and the average annual wages of the employer's FTEs must not exceed an amount equal to twice the dollar amount in effect under 26 C.F.R. sec. 1.45R-3(c)(2). Subject to certain adjustment and limitations, the tax credit is 50 percent of the eligible small employer's premium payments made on behalf of its employees under a qualifying arrangement or, in the case of a tax-exempt eligible small employer, 35 percent of the employer's premium payments made on behalf of its employees under a qualifying arrangement. Transition rules applied for 2014.

A charitable hospital also may not engage in extraordinary collection actions against an individual to obtain payment for care before it has made reasonable efforts to determine whether the individual is eligible for assistance for the care under its financial assistance policy.

Health insurance premium tax credit. Beginning in 2014, eligible individuals who purchase coverage under a qualified health plan (QHP) through an Exchange are allowed a premium tax credit under section 36B of the IRC, as added by section 1401 of the ACA. A married taxpayer is an "applicable taxpayer" only if he or she files a joint return with his or her spouse. Under a July 28, 2014, final rule, for taxable years beginning after December 31, 2013, through July 24, 2017, a married taxpayer will satisfy the joint filing requirement if he or she files a tax return using a filing status of married filing separately and is a victim of spousal abuse or abandonment.

$500,000 deduction for remuneration. On September 23, 2014, the IRS published a final rule implementing section 162(m)(6) of the IRC, as added by ACA sec. 9014, which generally provides that a covered health insurance provider's allowable deduction for remuneration attributable to services performed by an applicable individual in a tax year beginning after December 31, 2012, is limited to $500,000. The IRS defined "applicable individual" and provided for a de minimis exception.

Reporting. Pursuant to the IRS's March 10, 2014, final rule (79 FR 13220, March 10, 2014), generally, for calendar years beginning after December 31, 2014, providers of minimum essential benefits during a calendar year must file an information return and transmittal and furnish statements to responsible individuals pursuant to section 6055 of the IRC.

Standards for Exchanges and Qualified Health Plans

In a comprehensive May final rule (79 FR 30240, May 27, 2014), CMS updated a number of Exchange standards mandated by the ACA, including requirements relating to Navigators and non-Navigator assistance personnel; product discontinuation and renewal; standards/responsibilities of QHP issuers; and modification of reinsurance collections.

Reporting requirements. A May 7, 2014, final rule (79 FR 26113) amended 26 C.F.R. sec. 1.36B-5 to require Exchanges to report information on individuals enrolled in QHPs. For tax years ending after December 31, 2013, an Exchange must submit monthly and annual reports to the IRS containing information required by 26 C.F.R. sec. 1.36B-5(c) on all individuals enrolled in QHPs through the Exchange (excluding taxpayers obtaining health care coverage through a Small Business Health Options Program (SHOP)).

Premium stabilization programs. Premium stabilization programs established by the Affordable Care Act—risk adjustment, reinsurance, and risk corridors programs—are intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small group markets. In a March final rule (79 FR 13744, March 11, 2014), CMS updated these programs, including the agency's right to audit a state's program.

Ryan White HIV/AIDS Program. On March 19, 2014, CMS required (Final rule, 79 FR 15240, March 19, 2014) that issuers offering individual market QHPs, including stand-alone dental plans, accept third-party premium and cost sharing payments from the Ryan White HIV/AIDS Program; Indian tribes, tribal organizations, and urban Indian organizations; and state and federal government programs.

Eligibility and reenrollment determinations. On September 5, 2014, CMS published a final rule pursuant to ACA sec. 1411(f)(1)(B), which requires the Secretary to establish procedures to periodically redetermine the eligibility of individuals enrolled in a QHP through an Exchange. The final rule provides that beginning with annual redeterminations for the 2015 benefit year, an Exchange must redetermine the eligibility of a qualified individual on an annual basis using one of the procedures described in 45 C.F.R. sec. 155.335(a)(2). If an enrollee remains eligible for enrollment in a QHP plan through the Exchange upon annual redetermination and the product under which the QHP in which he or she was enrolled is still available, the individual's enrollment will be renewed unless he or she terminates coverage.

An Exchange must allow a QHP enrollee, or an application filer on behalf of the enrollee, to report changes with respect to eligibility standards via the channels available for the submission of an application. Beginning with annual redeterminations for the 2015 benefit year, the Exchange is permitted, but not required, to allow an enrollee or application filer to report changes via mail.

Group Health Plans

Public Health Service Act sec. 2708 prohibits a group health plan or health insurance issuer offering group insurance coverage from applying a waiting period that exceeds 90 days before an individual is eligible to enroll in the plan. In June, the Department of Labor, the IRS, and HHS issued a final rule (79 FR 35942) implementing section 2708 (see *Bona fide orientation periods finalized under ACA's 90-day waiting period limitation*, June 25, 2014).

Under amended 26 C.F.R. sec. 54.9815-2708, 29 C.F.R. sec. 2590.715-2708, and 45 C.F.R. sec. 147.116, for plan years beginning on or after January 1, 2015, if a group health plan or group health insurance issuer conditions eligibility on an employee's having completed a reasonable and bona fide employment-based orientation period, the waiting period may not exceed one month.

Basic Health Program and Medicaid

Section 1331 of the ACA required the establishment of the Basic Health Program (BHP). According to

CMS, a BHP is a program for low-income residents who would otherwise be eligible to purchase coverage through the Health Insurance Marketplace. Under the program, states can provide more affordable coverage for low-income residents and improve continuity of care for people whose income fluctuates above and below Medicaid and CHIP levels.

In March 2014, CMS released a final rule implementing the BHP and describing eligibility and operational standards, effective January 1, 2015 (see *HHS implements Basic Health Program under the ACA*, March 12, 2014). To participate in the program, a state is required to submit a Blueprint to CMS. That same day, CMS provided the final methodology and data sources to determine the federal payment amounts made to states in program year 2015 that establish a BHP.

Minnesota was the first state to establish a BHP, with coverage beginning January 1, 2015.

Medicaid. In January 2014, CMS amended Medicaid regulations pursuant to section 2601 of the ACA, which added Soc. Sec. Act sec. 1915(h)(2) to provide authority for a five-year duration for certain demonstration projects or waivers under sections 1115, 1915(b), (c), or (d) of the Social Security Act when they provide medical assistance to individuals who are dually eligible for both Medicaid and Medicare benefits. It also amended regulations pertaining to home- and community-based services.

Parts C and D

A May 23, 2014, final rule (79 FR 29843) on Medicare Parts C and D included several provisions implementing the ACA, among them the requirement that a Medicare Advantage (MA) organization must report and return Medicare overpayments it received no later than 60 days after the date on which it identified that it received an overpayment. Further, under ACA sec. 6408, CMS may impose intermediate sanctions or CMPs against an MA organization that enrolls an individual in any MA plan without prior consent, transfers an individual to a new plan without prior consent, fails to comply with marketing restrictions, or employs anyone that engages in this prohibited conduct. The final rule also established that an MA organization may appeal the findings of the applied methodology if the Part C recovery audit contractor did not apply its stated payment methodology correctly.

Conclusion

This year CMS and other federal agencies have implemented numerous ACA provisions through final rules, and 2015 could be just as productive. The contraceptive mandate will likely be modified in 2015, as the IRS, HHS, and EBSA issued a proposed rule in August in response to *Burwell v Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), that would modify the definition of an "eligible organization" that can avail itself of the accommodation. The Medicare Shared Savings Program, as established by ACA sec. 3022, is also likely to be the subject of a final rule in 2015 since CMS proposed major modifications to accountable care organizations in December.