House Passes The American Health Care Act of 2017

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Introduction

The opening salvo in the report from the House Committee on the Budget, committed to the Committee of the Whole House, reads as follows: “What is often called President Obama’s ‘signature’ achievement is now well known to be a defining failure.” This article will attempt to review H.R. 1628, the American Health Care Act (“AHCA”), passed in the House of Representatives on May 4, 2017, as dispassionately as possible recognizing that “legislation is the art of compromise.”

Before reviewing the provisions of what is admittedly a relatively short piece of legislation, one should ask to what extent does H.R. 1628 constitute a repeal and replacement of existing healthcare legislation. To do so it is helpful to understand the nature of the budget reconciliation process. Reconciliation, as created by the Congressional Budget Act of 1974, limits the legislative process to a consideration of taxing, spending, and federal debt limitations. The AHCA was submitted as a reconciliation bill pursuant to Title II of S. Res. 3, the concurrent resolution on the budget for fiscal year 2017.

Recognizing the limitations of the reconciliation procedure, the Report of the Committee on the Budget that accompanies H.R. 1628 [Report 115-52] speaks of a three-pronged attack to effectuate repeal, the subject legislation, as so limited, being the first prong. The second step will advance through the “fourth” branch of the federal government, that is, by means of the administrative law process through the promulgation of interpretative and legislative regulations. Executive Order 13765 [Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal; January 20, 2017] was the opening initiative on this second front. Secretary Tom Price of the Department of Health and Human Services then had new proposed regulations issued to “reduce the number of special enrollment periods; require 100-percent verification with documentation for special enrollment periods; and shorten the open enrollment period deadline from 31 January to 15 December, encouraging full-year coverage.” The third step in the repeal process would be additional legislative action outside the reconciliation restrictions, thereby subject to a potential Senate filibuster. Such legislation might permit the selling of health insurance across individual state boundaries, the implementation of tort
Prestigious Heritage

What a good looking group! The picture below was taken at the Council Dinner held during the Health Law Section’s premier live program, Emerging Issues in Healthcare Law. We had the privilege of hosting nine of the Section’s past chairs. The event is a highlight of the year for the Council, as current members of the Council experience the traditions of the Section that began 20 years ago when a small group of the most prestigious health lawyers determined that the ABA needed to have a national voice on health law matters. Rising from the ranks of a Health Law Forum in the ABA, the Section has developed both in terms of numbers and importance in the health law bar.

The men and women who have led the Section exemplify the diversity of the Section’s members. The Section’s chairs have been members of large law national and even international firms, small, boutique firms, in-house counsel, and government attorneys. They have hailed from Washington, D.C., Kentucky, Tennessee, Texas, Alabama, California, New Mexico, Indiana, Oregon, Virginia, Illinois, Minnesota, New York, Maryland, and now Mississippi. On a personal note, the past chairs have been the most encouraging mentors on my journey through leadership in the Section. One of my favorite memories of this year as chair is looking at the second row in the meeting hall on the opening day of Emerging Issues in Healthcare Law while I was delivering the State of the Section address, and seeing a row of past chairs smiling encouragingly at me while I bragged about our Section leadership. The past chairs love the Section and the contributions the Section has made to the health law bar.

In an effort to continue to capture the wisdom of the past chairs in the continued development of the Section, continued on page 10
reform, and elimination of the Independent Payment Advisory Board.\(^4\)

With that very brief introduction to the House legislation, a comparison of the AHCA with existing law will permit one to obtain a better appreciation of the direction in which the nation’s healthcare system may be headed.

**Individual Mandate**\(^5\)

I.R.C. Section 5000A [Requirement to Maintain Minimum Essential Coverage] requires an applicable individual (United States citizens and legal residents) and any dependent of such individual to be covered for each month commencing after 2013 under minimum essential health insurance coverage. Failure to satisfy such coverage requirement will subject the individual to a “shared responsibility payment”.\(^6\) Under H.R. 1628, the tax penalty for not having minimum essential coverage is repealed effective January 1, 2016.\(^7\) In its place Section 133 [Continuous Health Insurance Coverage Incentive] of Subtitle D [Patient Relief and Health Insurance Market Stability] imposes a flat 30 percent late-enrollment surcharge if an insurance applicant went longer than 63 days without continuous health insurance coverage. The surcharge would be discontinued after 12 months of coverage and would commence beginning in open enrollment for benefit year 2019. The Patient Protection and Affordable Care Act (“PPACA”) imposed this fundamental mandate so that the insurance pool would include a significant population of young healthy individuals whose absence will now presumably result in considerably higher health insurance premiums for the remaining older and sicker participants.

**Premium Subsidies to Individuals**\(^8\)

Presently, I.R.C. Section 36B [Refundable Credit for Coverage Under a Qualified Health Plan] and Section 1412 [Advance Determination and Payment of Premium Tax Credits and Cost-Sharing Reductions] of PPACA provide refundable and advanceable premium tax credits to qualified individuals whose incomes are between 100 to 400 percent of the Federal Poverty Level and who purchased coverage through the insurance exchanges.\(^9\)

To appreciate the magnitude of the credit, for a 64-year-old, the national average tax credit in 2017 is $12,068 at 100 percent of the Federal Poverty Level. The AHCA, for 2018 and 2019, would for income above 150 percent of the Federal Poverty Level increase credit amounts for young adults, but decrease such credits for adults that are age 50 years and older; the limitation on excess advance payments would no longer apply; the credits may be applied to purchase catastrophic plans; the credits may not be used for health plans that include abortion coverage; and credits are available even for plans acquired outside of an exchange, but no advance payments would be available. Beginning in 2020, annual premium credit amounts are adjusted for age (for example, $4,000 per individual age 60 and older) and such amounts begin to phase out depending on income level, filing status, and age (for example, the premium assistance tax credit would be reduced to zero at income of $230,000 for couples age 60 or older). Ostensibly both the changes in the individual mandate and premium subsidies continue to recognize the validity of the “three-legged” stool, but at a considerably lower level.\(^10\) And while the forced consumption of “broccoli” has been somewhat alleviated, the element of compulsion in a far weakened form is present still.\(^11\)

**Cost-Sharing Subsidies to Individuals**\(^12\)

Under existing law, Section 1402 of PPACA provides an eligible individual who enrolls in a qualified health plan through an exchange and whose household income exceeds 100 percent but does not exceed 250 percent of the Federal Poverty Level receives certain cost sharing subsidies based on the increase in the actuarial value of such plans.\(^13\) As a result of the increase in actuarial value, deductibles, copayments, coinsurance, and out of pocket expenses are reduced for all four “metallic” (bronze, silver, gold and platinum) tiers. The AHCA would repeal such cost sharing subsidies effective January 1, 2020. The House of Representatives had successfully sued the Secretaries of Health and Human Services and the Treasury in the Federal District Court in the District of Columbia to cease such cost reduction payments for the failure of Congress to appropriate public monies. With the change of administrations in the executive branch, the District of Columbia Circuit Court of Appeals continued the stay of the injunction order of the lower court’s decision until May 22, 2017. The Department of Justice and House Republicans have since requested further postponement. If the current administration wishes to pursue the appeal, the District Circuit will review the lower District court’s decision on the merits. Failure to prosecute the appeal may well make the cost-sharing reductions unavailable under PPACA given the present Congressional makeup.

**Individual Health Insurance Market Rules**\(^14\)

The rating variation permitted for the factor of age, which is limited under PPACA to a 3 to 1 ratio. Under the AHCA, starting January 1, 2018 an age rating ratio of 5 to 1 is permitted, unless a state adopts a different (presumably higher) ratio. Most importantly, states that use grants from the newly established Patient and State Stability Fund\(^15\) for high risk pools may continued on page 4
apply for a waiver of community rating (thus permitting health status as a rating factor) for individual market participants who fail to maintain continuous coverage. Both such age and health factors coupled with reduced premium and cost sharing subsidies may well make the concept of “access to health insurance” quintessentially meaningless.

Benefit Design

The requirement to include the 10 essential health benefits designated in Section 1302(b)(1) of PPACA for the individual and small group markets remains unchanged. However, commencing in 2020, states may seek waivers to re-define the constituent essential health benefits for health insurance coverage that is offered in the individual or small group market. PPACA’s specific actuarial values from 60 percent to 90 percent associated with the four metallic categories would sunset on December 31, 2019. While supposedly the prohibition of lifetime and annual dollar limits are not changed, such limits are tied to the essential health benefits, which are subject to change under state waiver authority. Once a particular jurisdiction waives some of the essential health benefits, the tie may be severed and the prohibition of lifetime and annual benefits may be eliminated.

Women’s Health

The prohibition of gender rating under PPACA remains unchanged. The AHCA would enact an immediate one-year prohibition against Medicaid funding for Planned Parenthood clinics. For those states electing Medicaid block grants, family planning would cease to be a mandatory covered service. Effective in 2018, a qualified health plan would be redefined to exclude abortion coverage other than those services permitted under the so-called Hyde Amendment (saving life of the woman or in cases of rape or incest). Insurers would not be prohibited from offering individual policies to cover abortion but no tax credits would be available.

Health Savings Accounts

Changes to health savings accounts that would become effective on January 1, 2018 include (1) an increase in the annual tax-free contribution limit to equal the limit on out-of-pocket cost sharing of qualified high-deductible plans ($6,550 – self only coverage; $13,100 – family coverage in 2017); (2) the alteration of the qualified medical expenses definition to include over-the-counter medications; and (3) a reduction in the penalty for distributions not used for qualified medical expenses from 20 percent to 10 percent.

High-Risk Pools

Section 1341(d) of PPACA in conjunction with a transitional reinsurance program for individual and small group markets directed states to eliminate or modify any state high-risk pool to the extent necessary to carry out the reinsurance program to cover individuals with pre-existing medical conditions (2010-2013). Under the AHCA states may use Patient and State Stability Fund grants to fund high-risk pools. By an amendment added after the Committee on the Budget submitted its report to the Committee of the Whole, as part of such fund, a new reinsurance plan, the Federal Invisible Risk Sharing Program (“FIRSP”), which the Centers for Medicare & Medicaid Services (“CMS”) will establish for states to administer, can be used to reduce the claims costs of specified high-risk individuals. Coverage will be provided by participating individual health insurance companies. Parameters, developed by CMS under which FIRSP will operate, include (1) health status statements to identify eligible individuals; (2) individuals diagnosed with specified conditions will automatically qualify; (3) health insurers may voluntarily qualify other individuals for FIRSP; (4) as determined by CMS, health insurers will pay a percentage of premiums for such eligible individuals to FIRSP; and (5) CMS will designate a threshold above which a proportion of claims that FIRSP will pay to health insurers.

Selling Insurance Across State Lines

Section 1333 of PPACA authorized regulations permitting compacts among two or more states to enter into agreements for offering health plans in the individual markets in all such states. The House, under the reconciliation procedure, chose not to include in the AHCA a provision for the sale of health insurance across state boundaries.

Exchanges

The state exchanges established by PPACA continue. There is no provision in the House legislation that prevents the federal government from establishing an exchange if a state chooses not to establish its own exchange. While premium tax credits, as amended, may be claimed even if health insurance is not purchased through an exchange, advance payments to the insurance companies is only available for policies purchased through an exchange.

Dependent Coverage

Extension of dependent coverage under Section 2714 of PPACA is available for an adult child until the child turns 26 years of age. The House legislation retains this provision.

Other Private Insurance Standards

The amendments found in Title X [Strengthening Quality, Affordable Health Care for All Americans] of PPACA, more specifically, amending Section 2718(b)(1)(A)(i) and (ii) of the Public Health Service Act, provide
for annual rebates to enrollees if the cost of clinical services and activities that improve healthcare quality is less than 80 percent of the premium revenue in the small group market or the individual market, or is less than 85 percent in the large group market. The House legislation does not change these minimum medical loss ratio standards.

Employer Requirements and Provisions

Similar to the repeal of the individual mandate, the AHCA repeals retroactively to January 1, 2016 the shared responsibility payments of large employers (50 full-time employees on business days during the preceding calendar year) found in I.R.C. Section 4980H. The penalties were of two kinds: (1) large employers not offering health coverage ($2,000 per employee) and (2) large employers offering coverage with employees who qualify for premium tax credits or cost-sharing reductions ($3,000 per employee). The AHCA also repeals the credit for employee health insurance expenses of small employers under I.R.C. Section 45R, effective January 1, 2020.

Medicaid

Possibly the most dramatic provisions contained in the AHCA pertain to Medicaid. Students, studying the United States Constitution, wax eloquent when describing the separation of powers. Less attention is typically paid to the limitations on federal legislative power that gave rise to the concept of federalism, a word that does not explicitly appear in the document.26 Fifty independent laboratories percolating different versions of state law is a thing to behold. One perhaps may state with some certainty that the citizens of these several states would like to have a federal health law that applies uniformly throughout the United States. So the question then becomes, in interpreting existing healthcare legislation and changes currently being contemplated thereto, when does Congress prefer uniformity and preempt the subject, and when does it choose to let federalism run rampant by allowing state law to affect the incidence of a federal health system?27

The AHCA’s proposal on Medicaid represents a highly significant change in a federal-state partnership that has operated for more than half a century. As behooves a partnership, participation of the states should be voluntary. PPACA, as originally enacted with respect to “forced” Medicaid expansion was found unconstitutional in Chief Justice Roberts’ majority opinion,28 which otherwise supported the constitutionality of the individual mandate under Congress’ spending power. As of March 30, 2017, 31 states and the District of Columbia have voluntarily accepted Congress’ invitation to expand Medicaid. Under PPACA, expanded Medicaid eligibility applies to non-elderly adults with incomes up to 138 percent of the Federal Poverty Level. By providing 100 percent of federal funding from 2014 through 2016, inclusive; 95 percent in 2017; 94 percent in 2018; 93 percent in 2019; and 90 percent in 2020 and thereafter, many governors and state legislators viewed the proposed expansion as the proverbial offer that could not be refused.

The “counteroffer” contained in the AHCA of 2017 would as of December 31, 2017 eliminate the option to extend coverage to adults with incomes (measured by modified adjusted gross income) above 133 percent of the Federal Poverty Level, limiting that reduced threshold to states that had adopted Medicaid expansion as of March 1, 2017, but sunsetting the above Federal Medical Assistance Percentages (“FMAP”) for those states as of January 1, 2020 subject to an exception for grandfathered enrollees who had enrolled through the Medicaid expansion as of December 31, 2019 as long as any break in eligibility does not exceed one month.

Most importantly, in the name of federalism, if one will, federal Medicaid financing will convert to a per capita29 limit beginning in fiscal year 2020. States with medical assistance exceeding the target amount for a fiscal year will have payments in the following fiscal year reduced by the amount of such excess payments. States will be given an option, for a period of 10 fiscal years commencing in fiscal year 2020, to elect to receive a Medicaid block30 grant instead of a per capita cap for children and for adults in non-expansion states.

Additional changes to Medicaid in the AHCA include (1) granting states the option to require work31 as a condition of eligibility for non-disabled, non-elderly, and non-pregnant enrollees as of October 1, 2017; (2) repealing the essential health benefits requirement; (3) repealing hospital presumptive eligibility provisions and presumptive eligibility for expansion adults;32 (4) prohibiting federal Medicaid funding for Planned Parenthood for one year; (5) requiring states to treat lottery33 winnings and other lump sum payments as income over a period of months in determining Medicaid ineligibility; (6) requiring states to limit home equity34 to a federal minimum of $500,000; and (7) requiring eligibility redeterminations35 to be made every six months for expansion enrollees beginning October 1, 2017.36

Medicare

The AHCA repeals the additional hospital insurance tax of 0.9 percent of self-employment income and of wages originally enacted by PPACA as amended by the Health Care and Education Reconciliation Act of 2010 for specified high thresholds of earned income.37 The increase in Medicare premiums, both Parts B and D, for high-income beneficiaries remains unchanged.

State Role

While mentioned above, it may be helpful to clarify how the AHCA would change states’ roles in health insurance. Under the AHCA, states are permitted to determine an age rating ratio. Absent state action, the federal standard ratio of 5 to 1 will apply. continued on page 6
The AHCA establishes a new Patient and State Stability Fund whose funds may be utilized to provide financial assistance to high-risk individuals, provide cost sharing subsidies for maternity and newborn care and for mental health and substance use disorder services. Under a reinsurance program administered by CMS, in the case of states that have not successfully applied for grants, the Fund will pay 75 percent of claims between $50,000 and $350,000. The Fund will receive $100 billion over nine years to permit grants to states for a default reinsurance program, fund $15 billion for a new FIRSP, and $8 billion over five years (2018-2023) for states that elect community rating waivers supplying financial assistance to insureds whose premiums are surcharged based on health status as a result of that waiver. In addition, states must match funding of seven percent in 2020, increasing to 50 percent by 2026. Grants will not be made to a state unless it agrees to make matching funds available. States will still have the option to establish a state based health insurance exchange, remembering that premium subsidies, effective January 1, 2018, will be available for health plans sold outside of exchanges.

Under Public Health Service Act Section 2701, starting in 2018 a state may apply for a waiver to permit an age rating ratio higher than 5 to 1. There is no upper limit to the ratio. Beginning in 2020, states will able to seek waivers to change the constituent elements of essential health benefits for health insurance coverage offered in the individual and small group markets. Commencing in 2019, or one year earlier for special enrollment periods, states that utilize the Patient and State Stability Fund grants to set up high-risk pools or reinsurance programs or that take part in FIRSP will be allowed to seek a waiver of the community rating requirement. States could then allow insurers to utilize health status as a rating factor for applicants in the individual market who have not maintained continuous coverage. This would replace the 30 percent late enrollment penalty, but similarly, the health status rating would only apply for one entire plan year.

Waivers are considered approved following submission of the waiver request unless the Secretary of Health and Human Services denies the application within 60 days of submission. An application for waiver must describe how the waiver would reduce average health insurance premiums, increase health coverage enrollment, stabilize the health insurance market, stabilize premiums for people with pre-existing conditions, or increase choice of health plans. The states will continue to administer the Medicaid provisions with federal matching funds available up to per capita limits or for certain population groups under block grants.

Financing

Under the AHCA the following taxes enacted by the Health Care and Education Reconciliation Act of 2010 as well as other financial changes are repealed effective January 1, 2017, unless otherwise indicated: (1) the individual shared responsibility payment and shared responsibility for employers regarding health coverage, effective January 1, 2016; (2) the so-called Cadillac tax on high-cost employer sponsored group health plans (suspended for taxable years 2020 through 2025, inclusive); (3) the increase in the hospital insurance portion of the self-employment and payroll taxes, effective January 1, 2023; (4) the 3.8 percent tax on net investment income for taxpayers whose adjusted gross income exceeds specified thresholds; and (5) taxes on tanning beds, health insurers, pharmaceutical manufacturers, and sale of medical devices.

The AHA also makes non-tax financing changes: (1) it eliminates the provision disqualifying reimbursement of costs for over-the-counter drugs reimbursed through a health savings account; (2) it removes the increase in penalty for non-qualified health savings account distributions; (3) it codifies the economic substance doctrine of I.R.C. Section 7701(o) for purposes of imposing a civil penalty in the case of an erroneous claim for refund; (4) it repeals the annual limit on contributions to flexible spending accounts; (5) it repeals the annual limit on deduction for salary in excess of $1 million paid to employees of publicly-held corporations under I.R.C. Section 162(m)(1); and (6) it reduces the percentage for phasing out the medical expense deduction based on adjusted gross income from 10 percent to 5.8 percent.

End of the Road for Repeal and Replace

Most citizens recognize that unlike the well accepted universal right to a quality education, The U.S. Constitution and federal statutory law do not support a right to universal healthcare. Reference is frequently made to the healthcare systems of other countries in the industrialized world, particularly in Europe. It has been suggested that the AHCA is more about tax reduction than in improving the healthcare system. The immediately preceding section labeled “Financing” would lend some support to that theme. The Tax Reform Act of 1986 succeeded in being enacted because of the politically flexible cast of characters who clearly understood that, as noted in the first paragraph of this article, “legislation is the art of compromise.” That quality of the legislator’s craft seems to be quite scarce if not totally absent in the current Congress.
Institute of CPAs (FICPA) (1985-1986); Chairman of the Committee on Continuing Professional Education, FICPA (1985-1986); Trustee of the FICPA Health Benefit Trust (1990-1997); Member of the International Taxation Committee, FICPA (2004 to 2006); Member of the State Legislative Policy Committee (2009-10) and a Member of the Standing Committee on Continuing Professional Education (2010-2014) [chairman 2013-2014]. He may be reached at js@kwalandolita.com.

Endnotes

1 Repealing and replacing so-called Obamacare continues to be a political struggle of major proportions. One perfect illustration comes from the radio transcript of the Sean Hannity program following the second United States Supreme Court decision interpreting the Patient Protection and Affordable Care Act of 2010 in King v. Burwell, 576 U.S. (2015), 115 AFTF 2d 2015-2203: “Now there are some very important things evident in this decision. We have now as a country – this is profound here – we have now reached a point where a majority of the Supreme Court of the United States of America, nine justices in black robes, have literally argued in this law, in this case, that words that are written into law are meaningless. That these words are empty vessels in the Supreme Court justices, these nine, if they choose, or majority thereof – they can fill any meaning they want into them.” Another less vitriolic example: Why would a budget hawk such as Senator Peter Domenici ever negotiate with a liberal such as Senator Edward Kennedy? “My daughter Clare, and it’s spelled c-l-a-r-e, she’s my fourth child of eight,’ Senator Pete V. Domenici began reluctantly, his voice soft and gravelly. ‘Clare was a beautiful girl. Now she’s all grown up, and she’s, well, she’s struggling. Struggling is a good word for it.” [Deborah Sontag, September 15, 2002, When Politics Is Personal (New York Times)].

2 The Byrd Rule, named after its chief sponsor, the late Senator Robert Byrd of West Virginia, allows senators to block provisions of reconciliation bills that are “extraneous” to reconciliation’s basic purpose of implementing budget changes. Without such a rule, committees receiving reconciliation directives would be free to add a wide range of unrelated provisions to their legislative recommendations, including provisions that might have difficulty passing under normal procedures. The Byrd Rule was adopted and then modified several times during the 1980s and finally included in the Congressional Budget Act in 1990, with only minor changes since then. Some have criticized it for excluding too much from reconciliation, such as provisions that might help reduce costs but for which specific savings estimates cannot be provided or provisions that would help make cost-saving changes work better.

“By the Byrd Rule applies only to action by the Senate, but because senators may invoke it during consideration of a conference report as well as initial Senate consideration of a reconciliation bill, it effectively constrains the House by limiting what the House can ultimately insist upon when compromising with the Senate.” Center on Budget and Policy Priorities (cbpp.org, accessed May 7, 2017).

3 45 C.F.R. Parts 147, 155 & 156.

4 The Board was created by the Patient Protection and Affordable Care Act with the authority to implement changes to the Medicare program subject to a Congressional override through a supermajority vote of the Senate. Black's [R. TN. Report characterizes the Board as “a group of unelected bureaucrats.” The three-step process is described in greater detail in the Report’s introduction.

5 Section 205 [Individual Mandate] of the American Health Care Act of 2017. All references to section numbers hereinafter cited are to the subject legislation unless otherwise indicated.

6 A lay person may be led to believe that this “penalty,” tax if one will, equals a semi de minimis $695 in 2016. A married couple with one dependent over 18 years of age and a household income of $22,499, however, would have a penalty of $5,714 that would rival the cost of health insurance for a federal government employee.

7 Executive Order 13765 caused the Internal Revenue Service to change its policy for the 2017 tax filing season. Rather than reject an individual income tax return for processing for failure to answer the question concerning healthcare coverage, “the IRS has decided to make changes that would continue to allow electronic and paper returns to be accepted for processing in instances where a taxpayer doesn’t indicate…coverage status.” Despite that statement on the federal government’s web site (irs.gov, accessed May 7, 2017), the author believes that a tax professional should not prepare and submit an income tax return that omits information of healthcare compliance.

8 Sections 201, 202 & 203 [Recapture Excess Advance Payments of Premium Tax Credits; Additional Modifications to Premium Tax Credit; and Premium Tax Credit, respectively].

9 The exchanges were created by PPACA. The state insurance exchanges are marketplaces, not insurers nor government-run health plans that provide access to the qualified health plans of participating insurers, providing information to consumers so that consumers may compare the insurance policies offered by the health insurers licensed in a given state. A state may operate its own marketplace, partner with the federal government to operate a marketplace, or allow the federal government to operate a federally facilitated marketplace.

10 Patterned after former Governor George Romney’s Massachusetts healthcare system, the so-called three-legged stool was absolutely indispensable to prevent the health insurance marketplace from going into a death-like spiral. First leg: No exclusion for pre-existing conditions and no additional premium attributable to such prior medical history (community rating). Second leg: The real “linchpin” would be the individual mandate. Third leg: Availability of government subsidies, both premium credits and cost-sharing reductions.

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See America’s Bitter Pill—Money, Politics, Backroom Deals and the Fight to Fix Our Broken Healthcare System by Steven Brill, pp 32-34.

11 Being forced to eat broccoli is an unconstitutional infringement upon one’s individual freedom. “The Government argues that the individual mandate can be sustained as a sort of exception to this rule, because health insurance is a unique product. According to the Government, upholding the individual mandate would not justify mandatory purchases of items such as cars or broccoli because, as the Government puts it, “[h]ealth insurance is not purchased on the same footing as a car or broccoli; it is a means of financing health-care consumption and covering universal risks.” Reply Brief for United States 19. But cars and broccoli are no more purchased for their “own sake” than health insurance. They are purchased to cover the need for transportation and food.

16 Section 136 [Permitting States to Waive Certain ACA Requirements to Encourage Fair Health Insurance Premiums] (Amendment by Mr. Tom MacArthur, R. N.J.).

17 The essential health benefits are ambulatory patient services, emergency services, hospitalization; maternity and newborn care; mental health and substance abuse disorder services, including behavioral health treatment, prescription drugs, rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

21 Section 132 [Patient and State Stability Fund].

22 From the minority views of the Energy and Commerce Committee: “[T]o the extent that states use these funds to set up high risk pools, the minority is concerned that quarantining the sickest patients in high risk pools is destined to fail and will not protect people with pre-existing conditions. Decades of experience with high-risk pools has proven that they do not work—they are expensive for states to administer, expensive for consumers to purchase, and offer poor coverage with high premiums and even higher deductibles. High risk pools were incredibly expensive for sick patients, sometimes charging up to 250 percent of what healthy patients paid for their health insurance. Deductibles were sometimes as high as $25,000 with annual limits as low as $75,000. Even with inadequate coverage and high deductibles, states still had difficulty funding high-risk pools, resulting in long waiting lists and the rationing of care for the sickest patients. Furthermore, as the repeal legislation has no federal standards or consumer protections associated with these state high risk pools, states would be free to impose annual and lifetime limits, coverage exclusions associated with a patient’s pre-existing conditions, and waiting periods.”

23 It should be noted that IRC Section 106 makes no reference to age, Notice 2010-38 states that the exclusion will also apply to a child that has not attained the age of 27.

24 Sections 206 and 204 [Employer Mandate and Small Business Tax Credit, respectively].

25 Section 112 [Repeal of Medicaid Expansion].

26 “What were the Framers talking about, that two governments give you more freedom than one? I mean, how does this work? How do you get more freedom if you have two governments than if you have one?....And federalism is one of the neglected subjects of the American political discourse...But every generation has to learn it all...over...again. Democracy isn’t inherited. It’s not something in your genes.” U. S. Supreme Court Justice Anthony Kennedy to students visiting the U. S. Supreme Court, recorded December 14, 1999, aired on C-SPAN’s “America and The Courts” program, August 25, 2001.

27 “Rather than having the Secretary of the U.S. Department of Health and Human Services exercise schoolmarm-like supervision over how state officials should organize their health insurance markets, as provided under the Patient Protection and Affordable Care Act, Congress should repeal such an intrusion. Instead, Congress should waive federal rules and regulations and allow states to experiment with big ideas. States can and should compete on a national stage and compete directly with each other in meeting the most difficult challenges in the health care system: how best to handle the sickest and the poorest persons who have the greatest difficulty in securing affordable health care and today are often confined to poorly performing government programs like Medicaid.” Robert Moffit, Senior Fellow, Heritage Foundation’s Center for Health Policy Studies [Reform Health Care on the Foundation of First Principles, 04/14/11 heritage.org].

28 “As for the Medicaid expansion, that portion of the Affordable Care Act violates the Constitution by threatening existing Medicaid funding. Congress has no authority to order the States to regulate according to its instructions. Congress may offer the States grants and require the States to comply with accompanying conditions, but the States must have a genuine choice whether to accept the offer. The States are given no such choice in this case: They must either accept a basic change.
in the nature of Medicaid, or risk losing all Medicaid funding. The remedy for that constitutional violation is to preclude the Federal Government from imposing such a sanction. That remedy does not require striking down other portions of the Affordable Care Act.” National Federation of Independent Business v. Sebelius, 132 S.C.t. 2566, 2608 (2012).

29 Section 121 [Per Capita Allotment for Medical Assistance].

30 The Flexible Block Grant Option for states was added as a Manager’s Amendment as Subsection (i) of Section 121.

31 Section 117 [Permitting States to Apply a Work Requirement for Non-disabled, Non-elderly, Non-pregnant Adults Under Medicaid (Manager’s Amendment)].

32 Presumptive eligibility was provided under Section 2202 of PPACA: “PERMITTING HOSPITALS TO MAKE PRESUMPTIVE ELIGIBILITY DETERMINATIONS FOR ALL MEDICAID ELIGIBLE POPULATIONS.”

33 Section 114(a) [Setting States Disenroll High Dollar Lottery Winners].

34 Section 114(d) [Updating Allowable Home Equity Limits in Medicaid].

35 Section 116 [Providing Incentives for Increased Frequency of Eligibility Redeterminations].

36 In theory, nothing contained in expanded Medicaid, as altered by the AHCA, is obligatory, as the entire Medicaid partnership is a voluntary one. Once a state chooses to accept the benefits of federal funding, then conditions, subject to waiver, naturally attach to participation.

37 I.R.C. §§ 1401(b)(2) and 3101(b)(2).

38 While a pre-existing condition cannot cause a denial of insurance coverage so that one has access to health insurance, premiums predicated on health history, in the absence of community rating, will, from a practical point of view, tend to close the access door. Federalism to enhance state innovations may not be good medicine for the state’s inhabitants.

39 Subject to an amendment proposed by Congresswoman Martha McSally (R. AZ), waivers would not apply to health benefits of members of Congress through health plans created under PPACA or offered through exchanges.

40 Most of the tax provisions are contained in Title II [Committee on Ways and Means], Subtitle A [Repeal and Replace of Health-Related Tax Policy], Sections 201 through 218, inclusive. Subtitle E, Section 251 provides for the repeal of the tax on net investment income.

41 For example, the author’s accounting firm prepared a federal individual income tax return for a gentleman that had sold three residences in 2014. The net investment income tax equaled $356,207, demonstrating quite convincingly that a low flat rate of tax applied to a large amount of taxable income must of necessity yield a large tax liability.

42 “A term used to indicate the presence of significant nontax economic possibilities associated with undertaking an activity or transaction, so as to permit deductions and losses with respect to the activity or transaction. The absence of economic substance renders the activity or transaction vulnerable to being classified as a sham (see Kretch v. U.S., 6 AFTR 2d 5851, 364 US 361, 5 L.Ed 2d 128, 60-2 USTC ¶ 9785 (1960), transaction incapable of creating economic effects aside from non-tax economic purpose or otherwise invalid). The definition is unsettled and is often said to include a business purpose component. Congress codified the doctrine prospectively in 2010 in limited circumstances to require both a change of economic position plus business purpose (apart from federal income taxes), by adding § 7701(o) to the Internal Revenue Code.” Warren, Gorham & Lamont Tax Dictionary.

43 In the context of constitutional adjudication, Associate Justice Antonin Scalia maintained that foreign law is an inappropriate source in interpreting the United States Constitution: “In any event, an ‘emerging awareness’ is by definition not ‘deeply rooted in this Nation’s history and tradition[,]’ as we have said ‘fundamental right’ status requires. Constitutional entitlements do not spring into existence because some States choose to lessen or eliminate criminal sanctions on certain behavior. Much less do they spring into existence, as the Court seems to believe, because foreign nations criminalize a conduct. The Bouyer’s majority opinion never relied on ‘values we share with a wider civilization,’ ante, at 576, but rather rejected the claimed right to sodomy on the ground that such a right was not ‘deeply rooted in this Nation’s history and tradition,’ 478 U. S., at 193-194. Bouyer’s rational basis holding is likewise devoid of any reliance on the views of a ‘wider civilization,’ see id., at 196. The Court’s discussion of these foreign views (ignoring, of course, the many countries that have retained criminal prohibitions on sodomy) is therefore meaningless dicta. Dangerous dicta, however, since this Court... should not impose foreign morals, fads, or fashions on Americans.” (emphasis added) Foster v. Florida, 537 U.S. 990 , (2002) (Thomas, J., concurring in denial of certiorari).” See also Lawrence v. Texas, 539 U.S. 558, 598 (2003)

44 In an opinion article in the Sunday Review of the New York Times on May 6, 2017, Peter Suderman entitles his article: The House Health Care Disaster Is Really About Taxes.

45 “The necessity of a senate is not less indicated by the propensity of all single and numerous assemblies to yield to the impulse of sudden and violent passions, and to be seduced by factious leaders into intertemporal and pernicious resolutions. Examples on this subject might be cited without number; and from proceedings within the United States, as well as from the history of other nations. But a position that will not be contradicted need not be proved. All that need be remarked is, that a body which is to correct this inirmity ought itself to be free from it, and consequently ought to be less numerous. It ought, moreover, to possess great firmness, and consequently ought to hold its authority by a tenure of considerable duration.”

ABA Section of Science & Technology Law book offers vital guidance and information for those involved in compliance with the Security Rule and Breach Notification Rule.

HIPAA and the Security Rule are sources of law, but the Security Rule also acts as a source of information security practices. A Guide to HIPAA Security and the Law, Second Edition bridges the gap between the law and information security practices. The Health Information Technology for Economic and Clinical Health Act, also called the HITECH Act, imposes additional security requirements. This book serves as a reference to a wide audience: healthcare and information security professionals implementing the HIPAA Security Rule and Breach Notification Rule, as well as attorneys and business professionals advising them.

Author Stephen S. Wu served as the 2010–2011 Chair of the ABA Section of Science & Technology Law and has authored or coauthored six books on information security and the law. Mr. Wu is an of counsel attorney with Silicon Law Group, a member of the ABA Section of Science & Technology Law, and an affiliate member of the American Law Institute. He is a frequent speaker on information security, robotics, and Internet of Things legal topics.

The Health Lawyer

Volume 29, Number 5, June 2017
we created the Past Chairs’ Advisory Board to provide advice to the Chair and Director on specific projects designated to the Board by the Chair and the Director. The Board is chaired by immediate past Section Chair, Bill Horton, a partner at Jones Walker in Birmingham, Alabama. The Board has been active this year on projects including work on the Section’s Strategic Plan and development of processes for appointment of the Section’s Board of Governors member.

The depth of knowledge and experience of this group is incredible. E. Paul Herrington, better known to us as the “Father of the Section” is the Associate General Counsel of Humana, Inc. in Louisville, Kentucky. Howard Wall, who was instrumental in developing the Section’s premier live program, is the Executive Vice President and Chief Administrative Officer, General Counsel and Secretary of Regional-Care Hospital Partners in Nashville. Greg Pemberton, who not only served the Section as Chair in 2005-2006, but also served as the Section’s House of Delegates member for 12 years, is now retired but practiced law for over 40 years at Ice Miller in Indianapolis. Tony Patterson, currently one of the Section’s delegates to the House of Delegates, served the Section as Chair in 2004-2005, practiced law at Norton Rose Fullbright in Texas for over 20 years and now serves as Chief Administrative Officer and General Counsel of Kalispell Regional Healthcare in Kalispell, Montana. Vickie Yates Brown is currently the appointed secretary of the Kentucky Cabinet for Health and Family Services. Vickie served as Chair of the Section in 2008-2009. Linda Baumann was instrumental in developing the Section’s premier policy live program called the Washington Health Law Summit. Linda served the Section as Chair in 2010-2011. Linda is a partner in the healthcare practice at Arent Fox in Washington, D.C.

Andy Demetriou served the Section as Chair from 2007-2008. Andy currently serves as a partner at Lamb & Kawakami in Los Angeles and a manager of Berkley Research Group where he provides advice on strategy, transactions and health analytics as well as expert services. While chair of the Section, membership grew to over 9,000 lawyers, students and associate members. Paul DeMuro, now practicing with Broad and Cassel in its Fort Lauderdale office, served as chair from 2006-2007. Under Paul’s leadership, the Section gained members and the Council had a memorable Council meeting in Germany.

The Section is known for its “Davids.” David Douglass developed the Section’s highly successful leadership training meeting, moving the meeting from September to July, and encouraging the Section’s officers to develop intensive training sessions. David served as chair in 2012-2013 and is co-managing partner of Sheppard Mullin’s D.C. office. David Hilgers completed an extensive Strategic Plan for the Section in 2010 and moved the Section to think innovatively to encourage membership initiatives. David is a member of Husch Blackwell’s Healthcare, Life Sciences & Education team in Austin, Texas. David Johnson led the Section as Chair in 2011-2012. David encouraged the Section to develop an ADR task force. He practices healthcare law at Montgomery & Andrews in Albuquerque, New Mexico.

Kathy Scully-Hayes served the Section as Chair from 2013-2014 and became the first chair from the Government Sector. Kathy is an Administrative Law Judge with the Social Security Administration in Maryland. Kathy brought a unique perspective to the Section and encouraged its growth in the government attorney sector. Michael Clark practices in the white collar crime area with his firm, Duane Morris, in Houston, Texas. Under Michael’s leadership in 2014-2015, the Section developed the framework for a Military and Veteran’s Task Force which was established last year during Bill Horton’s tenure as Chair.

The above named Chairs have influenced my time as a leader in the Section, but the other past chairs equally contributed to the growth and influence of the Health Law Section. Jay Christiansen served a two-year stint as chair from 1997-1999; Patricia Meador was the first female chair in 2000-2001. Robert Roth served from 2001-2002, Sara Keller from 2002-2003 and Bonnie Brier from 2003-2004. The Section and the greater ABA is proud to have such a prestigious heritage. Thank you all for your service to the Section and the health law bar.

Your Chair,
Joyce Hall

Mississippi Trivia: People don’t always think of Mississippi when they are interested in watching world class ballet, but, Jackson, Mississippi is one of only four cities in the world sanctioned by The International Theater-Dance Committee to host the International Ballet Competition. The other three are Moscow, Russia, Varna, Bulgaria and Helsinki, Finland.
The Editorial Board provides expertise in specialized areas covered by the Section. Individual Board members were appointed by the Interest Group Chairs and Editor Marla Durben Hirsch. If you are interested in submitting an article to The Health Lawyer, you may contact one of the Editorial Board members or Ms. Hirsch. With the establishment of the Editorial Board, the Section strengthens its commitment to provide the highest quality analysis of topics in a timely manner.

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Our experts have specialized experience in:

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- FINANCIAL ADVISORY SERVICES
- BANKRUPTCY AND RESTRUCTURING
- CLINICAL ECONOMICS
- PERFORMANCE IMPROVEMENT
Introduction

On January 17, 2017, the Department of Health and Human Services (“HHS”) issued a final rule entitled “Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures” (the “Final Rule”). In the Final Rule, HHS strives to improve efficiencies for appellants and adjudicators and increase decision-making consistency across appeal levels. In so doing, HHS is attempting to alleviate the significant backlog of pending appeals at the Administrative Law Judge (“ALJ”) and Medicare Appeals Council (“Council”) stages of appeal. HHS has a three-pronged strategy for alleviating the backlog of pending appeals:

1. Invest new resources at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog.
2. Take administrative actions to reduce the number of pending appeals and encourage resolution of cases earlier in the process.
3. Propose legislative reforms that provide additional funding and new authorities to address the appeals volume.

The Final Rule became effective on March 20, 2017. This article examines many important provisions of the Final Rule and their effect on Medicare appellants as well as their potential effect on the appeals backlog.

Contents of the Final Rule

General Provisions

Precedential Final Decisions of the Secretary

Prior to the enactment of the Final Rule, Council decisions were binding only on the parties to a particular appeal; they did not have precedential value. In the Final Rule, HHS finalized a proposal to grant precedential authority to certain Council decisions. The Chair of the Department Appeals Board (“DAB”) is tasked to designate which Council decisions will be made precedent. Notice of decisions designated as precedent will be made through the Federal Register and posted on a page of HHS’s website. Precedential Council decisions are binding on all lower-level decision makers from the date that the decisions are posted on HHS’s website.

In applying a precedential Council decision to future cases: (1) the Council’s legal analysis and interpretation of an authority, binding provision, or provision that is owed substantial deference is binding on future determinations and appeals in which the same authority or provision is applied (and in which the authority or provision remains in effect); and (2) factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts remain the same. The goal of granting precedent authority to certain Council decisions is to provide adjudicators with direction on repetitive issues and increase predictability for appellants throughout the appeals process to guide their decision-making regarding which claims to appeal.

In response to commenters’ concerns regarding the criteria the Chair of the DAB will use to determine which Council decisions to make precedent, HHS acknowledged the commenters’ concerns but declined to specify a comprehensive set for criteria for the Chair of the DAB to follow in making such designations. However, as finalized, the regulations provide the following high-level guidance:

42 C.F.R. § 401.109(a). In determining which decisions should be designated as precedent, the DAB chair may take into consideration decisions that address, resolve or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.

To ensure consistent application of the precedent Council decisions, HHS intends to perform joint training sessions involving the Centers for Medicare & Medicaid Services (“CMS”), The Office of Medicare Hearings and Appeals (“OMHA”) and the Council to educate the adjudicators at each level of appeal regarding the precedent Council decisions. In terms of providing similar education to the appellant community, HHS noted that “education sessions may also be appropriate during forums where the public participates, such as the OMHA Appellant Forum.”

Attorney Adjudicators

The Final Rule expands OMHA’s available adjudicator pool by granting authority for attorney adjudicators. Attorney adjudicators can now issue decisions where an ALJ hearing is not
required (ALJs will retain sole responsibility for presiding over ALJ hearings). Examples of situations in which attorney adjudicators may issue decisions (i.e., where an ALJ hearing is not required and a decision may be made by an attorney adjudicator based on the written record) include the following:

- Where the evidence in the hearing record supports a finding in favor of the appellant(s) on every issue; if the parties agree in writing that they do not wish to appear before an ALJ at a hearing; and/or if a stipulated decision is appropriate \(^1\) (see 42 C.F.R. §§ 405.1038);
- Where an appellant requests to withdraw its Request for ALJ hearing (see 42 C.F.R. §§ 405.1052 (a) (1));
- Where an appellant appeals a QIC or IRE \(^2\) dismissal (see 42 C.F.R. §§ 405.1004);
- Where remand to a Medicare contractor is appropriate to obtain information that can only be provided by CMS or its contractors (see 42 C.F.R. §§ 405.1034 (a)). \(^3\)

HHS estimates that based on fiscal year (“FY”) 2016 data, the addition of attorney adjudicators could redirect 24,500 appeals per year from the dockets of ALJs to attorney adjudicators, to be decided at a lesser cost to the government than if all cases were decided solely by ALJs. \(^4\)

Specific Provisions of Part 405 Subpart I

Appointed Representatives

Regulatory requirements for appointed representatives are in place to ensure that adjudicators communicate confidential information only with appropriate individuals. \(^5\) Prior to the enactment of the Final Rule, federal regulations (42 C.F.R. § 405.910 (c)) required a valid appointment of representative (“AOR”) to include the following elements:

1. Be in writing and signed and dated by both the party and individual agreeing to be the representative;
2. Provide a statement appointing the representative to act on behalf of the party, and in the case of a beneficiary, authorizing the adjudicator to release identifiable health information to the appointed representative;
3. Include a written explanation of the purpose and scope of the representation;
4. Contain both the party’s and appointed representative’s name, telephone number and address;
5. Identify the beneficiary’s Medicare health insurance claim number when the beneficiary is the party appointing the representative;
6. Include the appointed representative’s professional status or relationship to the party;
7. Be filed with the entity processing the party’s initial determination or appeal.

Sub-regulatory guidance, which was in place prior to the enactment of the Final Rule (i.e., Medicare Claims Processing Manual (“MCPM”) (CMS Internet-Only Publication 100-04, Chapter 29, Section 270.1.2) \(^6\) and CMS’s Appointment of Representative Form (Form CMS 1696)), \(^7\) and which presently remains in effect, requires a valid AOR to include a unique identifier to identify the individual or the entity represented (i.e., Medicare Health Insurance Claim Number (“HICN”) if a beneficiary is the represented party and the National Provider Identifier Number (“NPI”) if a provider or supplier is the represented party). The Final Rule revised the federal regulations to mirror existing sub-regulatory guidance to require that where a represented party is a provider or supplier, a valid AOR must include the NPI of the Medicare provider or supplier. \(^8\)

The Final Rule also revised the regulatory requirements for delegation of an AOR, in particular with respect to delegations by one attorney to another within a law firm. Generally, an appointed representative is prohibited from designating another individual to serve as an appointed representative unless the representative provides written notice to the party of his or her intent to delegate and the delegatee accepts the designation, evidenced by a written statement signed by the party. \(^9\) A delegation is effective when an adjudicator receives notice of the delegatee’s acceptance. \(^10\) Pursuant to the Final Rule, a written statement signed by the party is not required when an appointed representative and his or her designee are attorneys in the same law firm or organization, and the notice of intent to delegate indicates this. \(^11\)

CMS and/or CMS Contractors as Participants or Parties to the Adjudication Process

In the Final Rule, HHS attempted to simplify proceedings when CMS or CMS contractors are involved. In particular, the Final Rule placed limitations on the number of entities (CMS or CMS contractors) that are permitted to serve as a participant or party in an ALJ proceeding and clarified the roles for hearing participants and parties. \(^12\) Prior to the enactment of the Final Rule, there were no limitations in place on the number of contractors that were permitted to participate in ALJ hearings (which created challenges in scheduling ALJ hearings, and further resulted in lengthier proceedings \(^13\) with oftentimes duplicative testimony presented by the contractors). The following chart summarizes the new limitations for Medicare Part A and Part B appeals:

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### When may a CMS contractor elect this status?

<table>
<thead>
<tr>
<th>NON-PARTY PARTICIPANT</th>
<th>PARTY</th>
</tr>
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<tbody>
<tr>
<td>42 C.F.R. § 405.1010</td>
<td>42 C.F.R. § 405.1012</td>
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There are three opportunities:
1. If no hearing is scheduled, no later than 30 calendar days after notification that a request for hearing was filed;
2. If a hearing is scheduled, no later than 10 calendar days after receiving the notice of hearing;
3. An ALJ may request, but not require, CMS and/or one or more of its contractors to participate in an ALJ hearing.

There are two possibilities (unless the request for hearing is filed by an unrepresented beneficiary, in which case CMS and its contractors would be precluded from electing party status):
1. Upon filing a notice of intent to be a party no later than 10 calendar days after the QIC receives the notice of hearing;
2. An ALJ may request, but not require, CMS and/or one or more of its contractors to be a party to a hearing.

### What are a CMS contractor’s roles and responsibilities in the proceedings on a request for ALJ hearing?

Participation includes filing position papers and/or providing testimony to clarify factual or policy issues in a case.

- **Timeframe to submit position papers and/or written testimony.** If no hearing is scheduled, a position paper or written testimony must be submitted within 14 calendar days of an election to participate; or
- If a hearing is scheduled, a position paper or written testimony must be submitted within five calendar days prior to the hearing, unless the ALJ grants additional time.

- **Copies.** If no hearing is scheduled, a copy of any submitted position paper or written testimony must be provided within 14 calendar days of an election to participate to the parties who were sent a copy of the notice of reconsideration.
- A copy of any submitted position paper or written testimony after a hearing is scheduled must be provided within five calendar days prior to the hearing to the parties who were sent a copy of the notice of hearing.
- If a CMS contractor fails to send a copy of its position paper or written testimony to the parties or fails to submit its position paper or written testimony within the timeframes discussed herein, the position paper or written testimony will not be considered in deciding the appeal.

CMS contractor participation does not include calling witnesses or cross-examining the witnesses of a party to the hearing.

The CMS contractor may not be called as a witness during the hearing and may not be subject to examination or cross-examination.

The CMS contractor may provide testimony to rebut factual or policy statements made by a participant.

The ALJ may question the participant about its testimony.

Parties may file position papers, submit evidence, provide testimony to clarify factual or policy issues, call witnesses and/or cross-examine the witnesses of other parties.

- **Timeframe to submit position papers and/or written testimony.** Any position paper, written testimony and/or evidence must be submitted no later than five calendar days prior to the hearing, unless the ALJ grants additional time.

- **Copies.** A copy of any position paper, written testimony, and/or evidence a CMS contractor submits to OMHA must be sent within the same timeframe to the parties who were sent a copy of the notice of hearing.

- If a CMS contractor fails to provide a copy of its position paper, written testimony, and/or evidence to the other parties, or fails to do so in the requisite timeframe, the position paper, written testimony, and/or evidence will not be considered in deciding the appeal.
| Limitation on participating in a hearing | • If a CMS contractor has been made a party to a hearing, no entity that elected to be a participant in the proceedings may participate in the oral hearing, but such entity may file a position paper and/or written testimony to clarify factual or policy issues.  
• If a CMS contractor did not elect to be a party to a hearing and more than one entity elected to be a participant in the proceedings, only the first entity to file a response to the notice of hearing may participate in the oral hearing. Entities that filed a subsequent response to the notice of hearing may not participate in the oral hearing, but may file a position paper and/or written testimony to clarify factual or policy issues in the case.  
• If a CMS contractor is precluded from participating in the oral hearing, the ALJ may grant leave to the precluded entity to participate in the oral hearing if the ALJ determines that the entity’s participation is necessary for a full examination of the matters at issue. If the ALJ does not grant leave to the precluded entity to participate in the oral hearing, the precluded entity may still be called as a witness by CMS or a contractor that is a party to the hearing.  
• If a CMS contractor or multiple contractors file an election to be a party to the hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing and the other entities are made participants in the proceedings, unless the ALJ grants leave to an entity to also be a party to the hearing.  
• An ALJ may grant leave to an entity to be a party to the hearing if the ALJ determines that the entity’s participation as a party is necessary for a full examination of the matters at issue. |
| Invalid election | • An election may be invalid if the election was not timely filed or the election was not sent to the correct parties.  
**Written notice of invalid election.** If no hearing is scheduled or the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the notice of decision, dismissal or remand is mailed.  
• If a hearing is scheduled, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than five calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and the written notice must be sent as soon as possible after the oral notice is provided.  
• An election may be invalid if the request for hearing was filed by an unrepresented beneficiary, the election was not timely, the election was not sent to the correct parties, or CMS or its contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity’s participation as a party is necessary for a full examination of the matters at issue.  
**Written notice of invalid election.** If the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the decision.  
• If the election was submitted before the hearing occurred, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than five calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and parties who were sent the notice of hearing must be sent written notice as soon as possible after the oral notice is provided. |

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HHS Seeks to Improve Medicare Appeals Process
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The new limitations are designed to streamline the ALJ scheduling and hearing process. Increasing ALJ hearing efficiencies should result in an increased caseload capacity, contributing to lessening of the backlog of appeals pending at the ALJ hearing stage of appeal.

Request for an ALJ Hearing or Review of a QIC Dismissal

1) Contents of Request for ALJ Hearing

As finalized by the Final Rule, pursuant to 42 C.F.R. § 405.1014 (a), a request for an ALJ hearing for a claim denial under Medicare Part A or Part B must include the following elements:

- The Request for an ALJ hearing or a review of a QIC dismissal must be made in writing. The request must include all of the following:
  - The name, address, and Medicare health insurance claim number of the beneficiary whose claim is being appealed, and the beneficiary’s telephone number if the beneficiary is the appealing party and is not represented;
  - The name, address, and telephone number of the appellant, when the appellant is not the beneficiary;
  - The Medicare appeal number or document control number, if any, assigned to the QIC reconsideration or dismissal notice being appealed;
  - The dates of service of the claim(s) being appealed, if applicable;
  - The reasons the appellant disagrees with the QIC’s reconsideration or other determination being appealed.
- The appellant must submit a statement of any additional evidence to be submitted and the date it will be submitted.32

In correlation with the Final Rule, in January 2017 Form CMS-20034 A/B “Request for Medicare Hearing by an Administrative Law Judge” was discontinued and replaced with Form OMHA-100, “Request for an Administrative Law Judge (ALJ) Hearing or Review of Dismissal.”33 The content criteria listed above to establish a complete request for ALJ hearing are included on Form OMHA-100.34

Regarding the evidence to be submitted with an appellant’s request for ALJ hearing, federal regulations include an early presentation of evidence requirement, which (absent good cause) generally prohibits new evidence from being submitted at the ALJ stage of appeal. Pursuant to 42 C.F.R. § 405.966 (a) (2):

Absent good cause, failure to submit all evidence, including documentation requested in the notice of redetermination prior to the issuance of the notice of reconsideration precludes subsequent consideration of that evidence.

In an effort to bring consistency to ALJs’ findings of good cause for consideration of new evidence, in the Final Rule HHS identified four circumstances in which good cause for submitting new evidence at the ALJ stage of appeal may be found (and limited the definition of good cause to these situations):

1. When the ALJ or attorney adjudicator determines that new evidence is material to an issue addressed in the QIC’s reconsideration and that issue was not identified as a material issue prior to the QIC’s reconsideration;
2. When the ALJ determines that new evidence is material to a new issue identified after the QIC’s reconsideration decision;
3. When the party was unable to obtain the evidence before the QIC issued its reconsideration and the party submits evidence that it made reasonable attempts to obtain the evidence before the QIC issued its reconsideration; and
4. Where the evidence was submitted to the QIC or another contractor prior to the QIC’s issuance of its decision.35

The Final Rule acknowledged challenges faced by both appellants and OMHA when requests for ALJ hearing involve cases involving statistical sampling and extrapolation. Therefore, the Final Rule established new regulatory requirements for requests for ALJ hearing involving statistical sampling and extrapolation.

- An appellant’s request for ALJ hearing must: (1) include all information in paragraphs (a) (1) and (a) (2) of 42 C.F.R. § 405.1014 (as quoted above) for each sampled claim; (2) be filed for all appealed claims within 60 calendar days from the date the party receives the last reconsideration for the sample claims (if they were not addressed by a single reconsideration);36 and (3) set forth the reasons the appellant disagrees with how the statistical sample and extrapolation was conducted.37

- The Final Rule also established a requirement that a request for ALJ hearing must contain all of the information set forth in 42 C.F.R. § 405.1012 (a) (1) (as set forth above) to be considered to complete. Supporting materials (e.g., position paper, reconsideration decision) may be submitted to provide the information necessary to complete the request. In the Final Rule, HHS noted that such information is necessary for an ALJ to prepare for an ALJ hearing. If a request is incomplete,
an appellant will be provided with an opportunity to cure and complete its request; if an appellant fails to complete its request in the timeframe specified by the ALJ, the appellant's request for ALJ hearing or review may be dismissed.38

2) Sending Copies of Requests for ALJ Hearing to All Parties

Prior to the enactment of the Final Rule, appellants were required to send their requests for ALJ hearing to all other parties to the reconsideration or dismissal; if an appellant failed to provide copies to all other parties to the reconsideration or dismissal, the ALJ's 90-day adjudication timeframe was extended until all required copies were provided.39 The Final Rule contained two important clarifications to this requirement.

First, prior to the enactment date of the Final Rule, the requirement to copy all parties to the reconsideration decision or dismissal extended to beneficiaries in overpayment cases involving multiple beneficiaries without liability on the claims.40 Notably, the QIC may, but was not required to, send copies of its reconsideration decision to beneficiaries without liability.41 The Final Rule amended the copy requirement such that appellants are now required to send copies of their request for ALJ hearing only to the parties who were sent a copy of the QIC's reconsideration decision or dismissal.42

Secondly, the Final Rule clarified what materials are considered part of a request for ALJ hearing and therefore must be submitted to the other parties. Prior to the effective date of the Final Rule, ALJs applied the regulatory copy requirement inconsistently. For example, some ALJs considered all materials submitted with a request to be part of the request for ALJ hearing (thus requiring that they be sent to other parties), while other ALJs did not consider accompanying materials to be part of the request for ALJ hearing.

The Final Rule clarified HHS's position that, if additional materials submitted with a request are necessary to complete the request, then such materials must be sent to the other parties as well (subject to HIPAA's limitations on disclosing personal information).43 In commentary to the Final Rule, HHS specified its position that if a brief or position paper explaining the reasons the appellant disagrees with the QIC's reconsideration is submitted with the request, then such brief or position paper must be sent to the other parties.44 However, if additional evidence is submitted (e.g., medical records) that generally is not required to complete a request for ALJ hearing, such evidence would not need to be sent. Rather, the appellant could summarize such evidence to the other parties and provide it to them upon request.45 HHS disagreed with commenters' concerns that such a requirement increases the amount of paperwork that an appellant is required to send to other parties.46

Pursuant to the Final Rule, that the appellant satisfied the copy requirement can be established via the following:

- Certification on the standard form for requesting an ALJ hearing or requesting a review of a QIC dismissal that a copy of the request is being sent to the other parties;
- An indication, such as a copy or “cc” line, on a request for hearing or request for review of a QIC dismissal that a copy of the request and any applicable attachments or enclosures are being sent to the other parties, including the name and address of the recipient;
- An affidavit or certificate of service that identifies the name and address of the recipient and what was sent to the recipient; or
- A mailing or shipping receipt that identifies the name and address of the recipient, and what was sent to the recipient.47

As was the informal practice of ALJs prior to the effective date of the Final Rule, the Final Rule established the regulatory authority for ALJs to grant appellants the opportunity to cure appeal defects related to their failure to copy all parties in receipt of a reconsideration decision or dismissal. If an appellant does not provide evidence that it submitted copies of its complete request for ALJ hearing to the other parties in receipt of a reconsideration decision or dismissal within a time frame specified by the ALJ, the ALJ may dismiss an appellant’s request for ALJ hearing or review.48

3) Place for a Hearing

Prior to the enactment of the Final Rule, federal regulations codified at 42 C.F.R. § 405.1020 made video-teleconference (“VTC”) the default mode of hearing. In the Final Rule, HHS noted that appellants and ALJs both preferred telephone hearings over VTC.49 In fact, 98 percent of ALJ hearings were conducted by telephone in 2015.50 For this reason, the Final Rule amended the default mode of ALJ hearings to be telephone, rather than VTC, for appellants other than unrepresented beneficiary appellants.51 For unrepresented beneficiary appellants, the default mode of ALJ hearings would remain VTC.52 Even though telephone was made the default mode of ALJ hearings for appellants other than unrepresented beneficiary appellants, the regulations as adopted allow for hearing by VTC or in person if good cause is shown.53 Examples of good cause for VTC include:

- Where the ALJ or appellant raises an issue with a witness's credibility;
- Where a party presents multiple witnesses, or the case presents complex issues (including appeals where a high volume of claims is at issue or involve a high dollar overpayment amount);

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• Where a party wishes to present visual or video evidence.54

4) Notice of Hearing / Issues

Prior to the enactment of the Final Rule, federal regulations codified at 42 C.F.R. § 405.1022 (b) (1) required a notice of hearing to specify the particular issues to be decided during the ALJ hearing. Generally speaking, the issues before an ALJ included all of the issues brought out in the initial determination, redetermination or reconsideration that were not decided entirely in a party’s favor. 42 C.F.R. § 1032 allowed an ALJ to consider new issues, provided that the ALJ notify the parties of the new issue before the start of the hearing. To consider a new issue, regulations required that the resolution of any new issue could have a material impact on the claim or claims that are the subject of an appellant’s request for ALJ hearing. Furthermore, it was required that resolution of the new issue was permissible under the rules governing reopening of determinations and decisions.55

Noting that the statement of issues required time to develop, the Final Rule amended the regulations such that a specific issue statement is no longer required.56 Rather, issues before the ALJ (or attorney adjudicator) include all of the issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination or reconsideration that were not decided entirely in a party’s favor.57

The Final Rule also placed limitations on an ALJ’s (or attorney adjudicator’s) ability to raise new issues. Under the Final Rule, an ALJ (or attorney adjudicator) may only consider a new issue if its resolution could have a material impact on the claim or appealed matter, and (1) there is new or material evidence that was not available or known at the time of the determination and that may result in a different conclusion, or (2) the evidence that was considered clearly shows on its face that an obvious error was made.58 This revision to the regulations is important, as it is unlikely that evidence that was not available at the time of initial determination, redetermination and reconsideration will arise at the third stage of the appeals process or obvious errors persist following two stages of de novo review (i.e., redetermination and reconsideration). Thus, in most cases, the scope of review at the OMHA level will be limited to issues raised at the underlying stages of appeal.59

5) Hearing Procedures

In its Final Rule, HHS described scenarios where a party or a representative impeded the ALJ from regulating the course of the ALJ hearing.60 Examples identified by HHS included where a party or representative continued to present testimony or argument on irrelevant issues or on a matter that the ALJ believes he or she has sufficient information to render a ruling or the ALJ has already ruled. Another example is where a party or representative is uncooperative, disruptive or abusive during the hearing.61

The Final Rule added provisions to 42 C.F.R. § 405.1030 (b) to address such circumstances. In particular:

• If an ALJ determines that a party or representative is uncooperative, disruptive or abusive after the ALJ has warned the party or representative to stop its negative behavior, the ALJ may excuse the party or representative from the hearing. If a party or representative is excused from a hearing, the ALJ is required to provide the excused party or representative with an opportunity to submit written statements and affidavits. The party or representative may request a recording of the hearing.62

Conclusion

The Final Rule adopted provisions that will impact the backlog of appeals at least to some extent (e.g., OMHA’s expansion of its adjudication capacity by using attorney adjudicators). Other provisions of the Final Rule are likely to impact the number of appeals moving forward (e.g., making certain Council decisions precedential is likely to result in cases decided earlier in the appeals process with fewer appeals filed at the ALJ stage of appeal, if there is relevant precedential case law on point). Time will tell whether these initiatives will result in a meaningful reduction to the appeals backlog. Attorneys representing healthcare providers and suppliers involved in the Medicare appeals process are well advised to closely review this Final Rule. Many provisions of the Final Rule impact the day-to-day practice in the Medicare appeals space. Review of forthcoming sub-regulatory materials (e.g., updates to the MCPM or the OMHA Case Processing Manual (“OCPM”)) is also recommended.

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Endnotes


3 Generally, the five-stage Medicare Part A and Part B appeals process is as follows:

   • Stage 1: Following receipt of an initial determination, a dissatisfied party may file a request for “reconsideration.” A request for reconsideration must be submitted in writing to the Medicare Administrative Contractor (“MAC”) that issued the initial determination. See Section 1869 (a) (3) (C) of the Social Security Act (42 U.S.C. §§ 1395f (a) (3) (C)), 42 C.F.R. §§ 405.942 and 405.950, and Medicare Claims Processing Manual (“MCPM”), Ch. 29, § 310, available at www.cms.gov/RegulationsGuidance/Guidance/Manuals/Downloads/clm10429.pdf.

   • Stage 2: If a party is dissatisfied with a reconsideration decision, it may file a request for “reconsideration.” A request for reconsideration must be submitted in writing to the Medicare Administrative Contractor (“MAC”) that issued the initial independent contractor (“QIC”) identified in the reconsideration determination. See Sections 1869 (b) and (c) of the Act (42 U.S.C. §§ 1395ff (b) and (c)), 42 C.F.R. §§ 405.970 and MCPM, Ch. 29, § 330.

   • Stage 3: If a party is dissatisfied with a reconsideration decision, it may file a request for ALJ hearing. See Sections 1869 (b) and (d) (1) of the Act (42 U.S.C. §§ 1395ff (b) and (d) (1)), 42 C.F.R. §§ 405.1000-1016, and MCPM, Ch. 29, § 330.

   • Stage 4: If a party is dissatisfied with an ALJ’s decision, it may file a request for Medicare Appeals Council (“Council”) review. See Sections 1869 (b) (1) of the Act (42 U.S.C. §§ 1395ff (b) (1)), 42 C.F.R. §§ 405.1100-1132, and MCPM, § 340.

   • Stage 5: If a party is dissatisfied with the Council decision, it may file a request for federal district court review. See Section 1869 (b) (1) of the Act (42 U.S.C. § 1395ff (b) (1)), 42 C.F.R. § 405.1136 and MCPM, Ch. 29, § 345.

Note of history, an appellant’s likelihood of success in the Medicare appeals process has been greatest at the ALJ stage of appeal, which is administered by the Office of Medicare Hearings and Appeals (“OMHA”). A November 2012 Report by the Department of Health and Human Services’ Office of Inspector General (“OIG”) reported that the QICs issued fully favorable results in just 20 percent of cases decided at reconsideration. In contrast, fully favorable ALJ decisions were issued in 56 percent of cases. The OIG noted that these differences were the result in different interpretations of Medicare policies, among other factors. The OIG further reported variances in appeals results based on claim type and appellant type, with Part A inpatient hospital appeals having the highest success rate at 72 percent. See OIG Report, “Improvements are Needed at the Administrative Law Judge Level of Medicare Appeals” (OEI-02-10-0340) at p. 12, November 14, 2012, available at https://oig.hhs.gov/oei/reports/oei-02-10-0340.pdf.

It is the point of view of HHS that due to (1) a sustained increase in the number of appeals submitted by appellants and (2) receipt of only nominal increases in funding, a significant backlog of appeals presently exists pending at the third and fourth levels of appeal. See “FACT SHEET: HHS Issues Final Rule to Improve the Medicare Appeals Process,” available at https://hhs.gov/sites/default/files/medicare-appeals-final-rule-fact-sheet-jan2017.pdf.

4 As of February 21, 2017, over 650,000 appeals were pending at the ALJ stage of appeal. Even with its three-pronged strategy for backlog alleviation, HHS does not believe it will be able to alleviate the backlog in the next four years. See American Hospital Association (AHA); Baxter Regional Hospital, Inc. dbha Baxter Regional Medical Center; Rutland Hospital Inc., dbha Rutland Regional Medical Center; and Covenant Health v. Thomas E. Price, in his official capacity of Secretary of HHS, filed Feb 21, 2017, available at https://ahaprg.content/17/f12221govopeningbrief.pdf.


5 Id. and see American Hospital Association (AHA); Baxter Regional Hospital, Inc. dbha Baxter Regional Medical Center; Rutland Hospital Inc., dbha Rutland Regional Medical Center; and Covenant Health v. Thomas E. Price, in his official capacity of Secretary of HHS, filed February 21, 2017, available at https://ahaprg/content/17/f12221govopeningbrief.pdf. For an extensive discussion of the backlog alleviation efforts implemented to date, see The Health Lawyer, “Medicare Appeals Adjudication Delay Update: Lawsuit Decided in Favor of Appellants (for Now),” by Jessica L. Gustafson, Esq. and Abby Pendleton, Esq., Volume 29, Number 3, February 2017 available at http://americanbar.org/content/dam/aba/administrative/healthlaw/health_moa premiums bi_healthlawyerv29_2903.authcheckdam.pdf.

6 82 Fed. Reg. at 4974.


8 Id. The DAB was established in 1973. It has authority over disputes arising under many HHS programs and has experience issuing precedential determinations within areas of its jurisdiction (e.g., Medicare enrollment appeals arising under 42 C.F.R. part 498 and National Coverage Determination (“NCD”) and Local Coverage Determination (“LCD”) appeals arising under 42 C.F.R. part 426). The Council has been housed within the DAB since 1995 and serves under the leadership of the DAB chair, Id. at 4877.

9 Id. at 4978.

10 Id.

11 Note that the regulatory text at 42 C.F.R. § 401.109 (d) (1) specifically references Medicare authorities or provisions (and does not explicitly reference provisions that are owed substantial deference).

12 Id. at 4979. Note that if the underlying authority is revised, the Council decision would no longer have precedential value. Id. In addition, if a precedential Council decision is appealed to federal district court and overturned, it would no longer be precedential. Id. at 4981. With respect to factual findings, HHS clarified that its intent was to prohibit appellants from seeking a second bite at the apple. continued on page 20
HHS noted that many claim appeals turn on evidence of a beneficiary’s condition or care at the time care is rendered, and in such cases, findings of fact from prior precedential cases would not be binding. *Id.* at 4978.

13 *Id.* at 4979.
14 *Id.*
15 *Id.* See also 82 Fed. Reg. at 5105-5106.
16 *Id.* at 4981.
17 *Id.* In the Final Rule, HHS noted situations where CMS or one of its contractors participates in the proceedings before an ALJ and acknowledges either orally or in writing that an appealed item or service should be covered. *Id.* at 5072. Noting that such a situation is “ideal” for summary decision, the Final Rule provided authority for an ALJ or attorney adjudicator to issue a summary decision “in lieu of a full decision that includes findings of facts, conclusions of law and other decision requirements.” *Id.* However, even if CMS or one of its contractors indicates that it believes an appealed item or service ought to be covered, an ALJ or attorney adjudicator is not bound to issue a stipulated decision; rendering a stipulated decision would be optional. *Id.* at 5074.

From an appellants’ attorney point of view, although there are some cases where CMS or one of its contractors notifies an adjudicator of its belief that an appealed item or service ought to be covered, in many cases CMS does not provide such a concession; rather, CMS simply elects not to attend a particular hearing as a participant or party.

18 In the case of a Medicare Advantage (Medicare Part C) appeal, when a health plan maintains an initial adverse organization determination upon a reconsideration appeal, the plan submits its decision as well as the case file for review to the Part C Independent Review Entity (“IRE”). See Medicare Managed Care Manual, Chapter 13, Sections 80.3 through 90, available at https://cms.gov/Medicare/Appeals-and-Grievances/MMCA/IRE.html.
20 *Id.* at 4983.
21 *Id.* at 4995, citing 67 Fed. Reg. 69318-69319.
24 82 Fed. Reg. at 4995 and 5106.
26 *Id.*
27 *Id.* at 4996 and 42 C.F.R. § 405.910.
29 82 Fed. Reg. at 5020.

31 The requirement that unrepresented beneficiary appellants include their telephone numbers in requests for ALJ hearing is a new requirement established by the Final Rule. See 82 Fed. Reg. at 5032 and 5111.
32 82 Fed. Reg. at 5111.
34 Form OMHA-100 is available at https://hhs.gov/sites/default/files/OMHA-100-Request-for-Hearing-or-Review-of-Dismissal.pdf. If multiple beneficiaries are at issue in a single appeal, Form OMHA 100A may be included to comply with the content requirements for appeals involving multiple beneficiaries. Form OMHA 100A is available at https://cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS20034AB.pdf.
35 82 Fed. Reg. at 5055. See also 42 C.F.R. § 405.1028 (a) (2) and 82 Fed. Reg. at 5115-5116.
36 In a post-payment audit situation involving statistical sampling and extrapolation, many times MACs issue multiple demand letters associated with the alleged overpayment. For example, the MAC may issue one demand letter related to the extrapolated portion of the overpayment demand and additional demand letter(s) related to the claims comprising the sample. When multiple demand letters are issued, they are rarely issued on the same day. The failure of the MACs to issue simultaneous demand letters has complicated the Medicare appeals process for appellants and for adjudicators. From the perspective of appellants, when multiple demand letters are issued, it may be required to file numerous appeals related to one post-payment audit in order to meet deadlines for appeal (this is particularly so when an appellant submits an appeal under expedited appeal timeframes in order to meet the deadlines to avoid recoupment during the initial two stages of the appeals process). From the perspective of adjudicators, when multiple appeals related to one post-payment audit are submitted, there may be many different adjudicators rendering decisions related to the validity of the statistical sample and extrapolation performed. In the Final Rule, HHS declined to prohibit MACs from issuing multiple demand letters related to one overpayment demand (82 Fed. Reg. at 5033). The Final Rule’s provision allowing a request for ALJ hearing to be submitted 60 days following an appellant’s receipt of the final reconsideration decision related to the audit is HHS’s attempt to streamline the process.
37 82 Fed. Reg. at 5035-5034. See also 42 C.F.R. § 405.1014 (a) (3) and 82 Fed. Reg. at 5112-5113. If an appellant is unable to summarize his or her reasons for disagreement with the statistical sampling methodology and/or extrapolation, the appellant may submit a position paper or other documentation to explain the rationale for the challenge.
38 42 C.F.R. § 405.1014 (b1), 82 Fed. Reg. at 5034 and 5112.
39 42 C.F.R. § 405.1014 (b) (2).
40 Requirement previously codified at 42 C.F.R. § 405.1014 (b) (2).
41 See 42 C.F.R. § 405.976 (a) (2).
42 82 Fed. Reg. at 5036. See also 42 C.F.R. §405.1014 (d) and 82 Fed. Reg. at 5112.
43 *Id.*
44 *Id.*
45 *Id.*
46 *Id.*
47 *Id.* See also 42 C.F.R. § 405.1014 (d) (2) and 82 Fed. Reg. at 5112.
48 82 Fed. Reg. at 5036. See also 42 C.F.R. § 405.1014 (d) (3) and 82 Fed. Reg. at 5112.
49 82 Fed. Reg. at 5045.
50 *Id.*
51 *Id.* See also 42 C.F.R. § 405.1020 (b) (2) and 82 Fed. Reg. at 5114.
52 82 Fed. Reg. at 5045. See also 42 C.F.R. § 405.1020 (b) (1) and 82 Fed. Reg. at 5114.
53 82 Fed. Reg. at 5045. See also 42 C.F.R. § 405.1020 (b) (2) and 82 Fed. Reg. at 5114.
54 82 Fed. Reg. at 5049.
55 *Id.* at 5063.
56 *Id.* See also 42 Fed. Reg. § 405.1022 (b) and 82 Fed. Reg. at 5115.
57 *Id.*
58 82 Fed. Reg. at 5064. See also 42 C.F.R. § 405.1032 (b) and 82 Fed. Reg. at 5116.
59 Historically, when a claim was subjected to medical review at the redetermination and reconsideration stages of appeal, MACs and QICs were permitted to develop new issues and review all aspects of coverage for a claim or line item. In practice, in certain cases when an appellant cured the initial rationale for unfavorable initial determination, unfavorable appeal decisions were nonetheless based on different reasons. By way of MLN Matters Number SE1521 (most recently revised May 9, 2016 and effective for appeals submitted on or after April 18, 2016), CMS instructed MACs and QICs that:

For redeterminations and reconsiderations of claims denied following a complex prepayment review, a complex post-payment review, or an automated post-payment review by a contractor, CMS has instructed MACs and QICs to limit their review to the reason(s) the claim or line item at issue was initially denied. Prepayment reviews occur prior to Medicare payment, when a contractor conducts a review of the claim and/or supporting documentation to make an initial determination. Post-payment review or audit refers to claims that were initially paid by Medicare and subsequently reopened and reviewed by, for example, a Zone Program Integrity Contractor (ZPIC), Recovery Auditor, MAC, or Comprehensive Error Rate Testing (CERT) contractor, and revised to deny coverage, change coding, or reduce payment. Complex reviews require a manual review of the supporting medical records to determine whether...
there is an improper payment. Automated reviews use claims data analysis to identify improper payments. If an appeal involves a claim or line item denied on an automated pre-payment basis, MACs and QICs may continue to develop new issues and evidence at their discretion and may issue unfavorable decisions for reasons other than those specified in the initial determination.


60 82 Fed. Reg. at 5058.

61 82 Fed. Reg. at 5057.

62 Id. See also 42 C.F.R. § 405.1030 (b) (2) and 82 Fed. Reg. at 5116 and 42 C.F.R. § 432.2030 (b) (2) and 82 Fed. Reg. at 5132.

63 82 Fed. Reg. at 5058. See also 42 C.F.R. § 405.1030 (b) (3) and 82 Fed. Reg. at 5116 as well as 42 C.F.R. § 432.2030 (b) (3) and 82 Fed. Reg. at 5132.

64 The OCPM establishes day-to-day procedures for OMHA adjudicators carrying out their adjudicatory review functions. The OCPM is available at https://hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.
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David Ivers, Esq., Mitchell, Blackstock Ivers Sneddon & Marshall, PLLC, Little Rock, AR, is the latest Health Lawyer author to win a coveted Burton Award. His article, Conflict-Free Case Management On Collision Course with Integrated Care ran in the April 2016 issue of The Health Lawyer. This marks the fourth year in a row that an article from The Health Lawyer was selected for a Burton Award.

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Congratulations David!
PROACTIVELY RESPONDING TO GOVERNMENT INVESTIGATIONS USING DATA ANALYTICS: AN EXAMINATION OF DATA CONSIDERATIONS IN THE POST-ACUTE CONTEXT

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Picture this:

It is 10 a.m. on a Friday morning. Your day as in-house counsel for a nursing home chain is moving along normally. You finished your morning staff meeting and are prepping for a meeting with the Chief Financial Officer (“CFO”). Your administrative assistant knocks on your door to say that a government subpoena directed to your attention has just arrived. Your stomach sinks – not because you are aware of fraud but because you are aware of the headaches that come with responding to a government subpoena. You conduct an initial review of the subpoena and forward a copy for review to another member of the company’s legal team. Your colleague reports to you that he has heard rumors that the Department of Justice (“DOJ”) has been speaking with a former employee who previously worked in your finance department. Rumor has it that the former employee discussed being a party to several conversations in which both the Chief Executive Officer (“CEO”) and CFO pressured individuals running your different facilities to increase profits by admitting patients even if the circumstances were not warranted. This former employee also indicated that the CEO and CFO exerted pressure for lengths of stay to increase.

You have worked in post-acute care long enough to understand a few things. First, these allegations are serious. Second, these allegations, if true, would increase profits. Third, this is going to be a long investigation. For these reasons, it is not surprising that the DOJ’s interest was piqued as is yours.

You immediately sketch your next steps. Hire external counsel. Ensure a thorough and expeditious investigation. Determine if the allegations are true. If not true, then provide ample evidence to disprove the allegations. If true, then proactively calculate damages and negotiate a settlement with the DOJ.

Any response to an investigation of this sort should involve the use of data analytics. The government and its contractors are becoming increasingly more sophisticated in using data to develop theories of wrongdoing and to identify suspected fraudulent behavior. As a result, providers must be aware of their own data and the optics of that data. Providers should seek to use data, and analyses related to the same, to proactively monitor risk; to respond to government investigations; to dissuade the government from intervening in a False Claims Act (“FCA”) case; as a point of consideration in settlement discussions; and, if necessary, as a defense tool in FCA litigation.

While growth in post-acute spending has recently slowed, the Medicare program approximately doubled its post-acute spending between 2000 and 2015. As a result, the government seeks to ensure that the most appropriate (and cost-efficient) care is being provided and has relied on standard data analytics to identify anomalies in care patterns.

In making the case for the use of data in proactively responding to government investigations, this article focuses on data analytics and considerations in the context of post-acute providers, although the same concepts apply to all types of providers. This article also describes data monitoring activities undertaken by the government and how similar monitoring can and should be proactively implemented by providers. Finally, this article discusses the use of sampling in FCA investigations and litigation, a common approach for which data can play a significant role.

Reimbursement Overview

In order to appreciate potential risks and allegations in the context of government fraud investigations, and the use of data to respond to the same, one must consider the reimbursement methodology at issue. The following sub-sections provide an overview of Medicare’s reimbursement methodologies for various post-acute provider types and the key data elements for each. These key data elements are items that may be indicative of a provider manipulating the reimbursement system to garner more revenues/profits. As such, government prosecutors are increasingly relying on these key data elements to support theories of wrongdoing. Recognizing this, providers should be proactively monitoring their own metrics as they relate to the relevant data elements discussed below, and in the face of a government investigation, developing a defense strategy that accounts for, or puts in context, these data elements.

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Proactively Responding to Government Investigations Using Data Analytics

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Skilled Nursing Facilities (“SNFs”)

Reimbursement Overview: SNFs are paid a per diem payment for the provision of services to Medicare beneficiaries based on a prospective payment system (“PPS”), which means Medicare pays for services based on a predetermined, fixed amount. The SNF PPS payment covers all costs of furnishing covered Medicare Part A SNF services (routine, ancillary, and capital-related costs), with limited exceptions. The PPS payment for each resident is adjusted for case mix and geographic variation in wages. Case-mix adjustments are based on residents’ assessments, which classify residents into resource utilization groups (“RUGs”) based on the severity of residents’ medical conditions and skilled care needs. The determination of resource needs, or RUG category, is established using the Minimum Data Set (“MDS”), a standardized tool that assesses the resident’s clinical condition, functional status, and expected use of services.¹

Key Data Elements: There are several data elements to analyze when responding to DOJ investigations regarding whether or not a SNF has exploited incentives. These data elements provide a retrospective view of the facility’s operations. Primary among these data elements is the distribution of the number of days that a facility provides SNF services at each RUG level and the number of minutes of therapy being provided. It is helpful to understand how the distribution changes over time and whether the number of minutes of therapy has materially changed. Other patterns that can be assessed for abnormalities include the manner in which change-of-therapy assessments⁵ occur and the distribution between group/concurrent therapy. Additional patterns could include the percent of patients being readmitted to a short-term acute care hospital as well as the overall length of stay (“LOS”), especially for patients staying over 90 days. Another measure that will likely be considered when the DOJ investigates is the activities of daily living recorded at each patient’s assessment. The activities of daily living contain measures of how a patient performs daily living tasks (e.g., walking, eating, dressing). These daily living measures are not intended to measure performance or quality of care, and a facility should be cautious when either proactively using them or when responding to a DOJ inquiry.

Inpatient Rehabilitation Facilities (“IRFs”)

Reimbursement Overview: IRFs are freestanding rehabilitation hospitals or units in acute care hospitals that provide intensive rehabilitation services (i.e., at least three hours of intense therapy per day). IRFs are paid an amount of money each time that a patient leaves the facility (i.e., a per discharge payment) and this payment covers the provision of services to Medicare beneficiaries based on a PPS. The IRF PPS covers all costs of furnishing services (routine, ancillary, and capital related), with limited exceptions, such as costs related to operating certain educational activities. Reimbursement for each IRF patient is based on a patient assessment process where patients are classified into distinct groups based on clinical characteristics and expected resource needs. Patients are classified using the IRF Patient Assessment Instrument, which contains clinical, demographic, and other information. Separate payments are calculated for each group, including the application of case-mix and facility-level adjustments.⁶

Key Data Elements: When responding to a DOJ investigation related to an IRF, it is useful to understand the distribution of cases among the case-mix groups (“CMGs”) that Medicare uses for reimbursement. Certain CMGs offer larger reimbursement and/or a greater margin, making it imperative to understand the practice pattern at a facility. In a similar vein, one should understand the extent to which Medicare made outlier payments to the facility, for what cases, and for what time periods. Outlier payments are Medicare payments that are in addition to the payment calculated in accordance with the established payment methodology. This additional payment covers additional care that the patient received and that is considered by Medicare to be outside the normal amount of care expected by the payment methodology. A full analysis of readmissions is useful to understand the quality of care being provided. This would include readmissions to IRFs or short-term acute care hospitals. Lastly, the overall LOS should be analyzed to understand how it may have shifted.

Long Term Acute Care Hospitals (“LTCHs”)

Reimbursement Overview: LTCHs treat patients with multi-comorbidities requiring long-stay hospital-level care and are certified under Medicare as short-term acute care hospitals. LTCHs are generally defined as having an average inpatient length of stay (“ALOS”) of greater than 25 days and are excluded from the acute care hospital inpatient PPS. Instead, LTCHs are paid by Medicare under the LTCH PPS, based on prospectively set rates. The LTCH PPS classifies patients into distinct diagnostic groups based on clinical characteristics and expected resource needs. Payment for a Medicare patient will be made at a predetermined, per discharge amount pursuant to the patient’s assigned Medicare Severity Long-Term Care Diagnosis-Related Group (“MS-LTC-DRG”), which is based on diagnoses, procedures performed, age, gender, and discharge.
status. Medicare calculates the ALOS for each MS-LTC-DRG. If a patient's stay is five-sixths of the ALOS calculated by Medicare for that MS-LTC-DRG, then the LTCH will receive the full amount of Medicare’s payment. If the patient stays for less than five-sixths of the ALOS calculated by Medicare for that MS-LTC-DRG, then the LTCH will only receive five-sixths of Medicare’s payment. For example, if an MS-LTC-DRG has an ALOS of 30 days, and a patient stays in the LTCH for 25 days (5/6 of 30), the LTCH will receive the entire Medicare payment. However, if the patient is discharged on day 23, the facility will receive something less than the full payment.7

Key Data Elements: It is imperative to measure outlier payments when considering LTCHs, as the outlier thresholds can provide significant insight into a facility’s operations. A case at an LTCH can be considered a short stay and/or high cost outlier, both of which have ramifications on the amount of money received by the LTCH. It is important to analyze the historic readmission percentage either to the same LTCH or to a short-term acute care hospital. Specific diagnoses and procedures should also be analyzed, as these are often of interest during investigations since these diagnoses/procedures contribute significant revenue.

Hospice Providers

Reimbursement Overview: Medicare hospice providers are paid a daily payment rate for each day a patient is enrolled in the hospice benefit, which covers all costs incurred in furnishing services identified in a patient’s plan of care (whether provided directly by the hospice provider or arranged by the hospice provider), based on the level of care required to meet the patient’s and family’s need. The levels of care are (i) routine home care; (ii) continuous home care; (iii) inpatient respite care; and (iv) general inpatient care. Payments are made regardless of amount of services furnished on any given day. Effective January 1, 2016, a service intensity add-on (“SIA”) payment is available for services furnished at the end of life.8

Key Data Elements: Hospice providers must be aware and analyze the change in acuity of patients over time in conjunction with the change in LOS. During an investigation, it is also important to understand the distribution in each level of hospice care and how this changed over time. A key measure to understand the admission policies of a hospice is to analyze the discharge versus death ratio over time. Additional measures to be analyzed include the duration and continuity of home care and the distribution of the categories of care (e.g., routine home care, inpatient respite).

Home Health Agencies (“HHAs”)

Reimbursement Overview: HHAs are paid an episodic payment (for a 60-day episode of care) for the provision of services to patients under a home health plan of care based on a home health (“HH”) PPS. The HH PPS covers all services and supplies (whether provided directly by the HHA or under arrangement), except certain covered osteoporosis drugs and durable medical equipment. HH PPS payments are adjusted for case-mix and geographic differences in wages. With respect to the case-mix adjustment, payment rates are based on characteristics of the patient and his or her corresponding resource needs (e.g., diagnosis, clinical factors, functional factors, and service needs), as reflected in the Outcome and Assessment Information Set (“OASIS”).9 Based on the OASIS, patients are classified into Home Health Resource Groups. The HH PPS allows for outlier payments to be made for episodes with unusually large costs that exceed a threshold amount. Low-utilization payment adjustments are also available for patients who require four or fewer visits during the 60-day episode. Finally, a partial episode payment adjustment is available when a patient elects to transfer to another HHA or is discharged and readmitted to the same HHA during the 60-day episode.10

Key Data Elements: Similar to hospice providers, HHAs need to analyze the acuity of patients over time. Unlike other post-acute care providers that are paid for a single episode, Medicare pays HHAs for a length of time/episode. As such, one must analyze the number of episodes for each beneficiary within this time period. Additionally, understanding how, over time, both low and high utilization episodes have changed is helpful.

The Government’s Data Monitoring Activities

In addition to understanding the key data elements at issue, it is also important to understand how these data elements may be monitored or examined by the government.

In 2002, Congress passed the Improper Payment Information Act (“IPIA”) to “provide for estimates and reports of improper payments by federal agencies.”11 This Act covered improper payments by all federal agencies, and Congress did not constrain the law to the Medicare program. However, as the Medicare program accounts for a significant portion of the federal budget, this law brought additional scrutiny to the Medicare program. The law required Medicare, like other federal programs, to estimate the amounts of payments improperly paid and report the measures taken to reduce the improper payments.

Congress amended the IPIA in 2010 via the Improper Payments Elimination and Recovery Act12 and in 2012 via the Improper Payments Elimination and Recovery Improvement Act,13 expanding the requirements to include recovering improper payments.

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The IPIA, as amended, provided for the creation of the Hospital Payment Monitoring Program, which created several standard reports, including:

- Program for Evaluating Payment Patterns Electronic Report ("PEPPER"), which supports compliance efforts by publishing payment risks and targets tailored to facility type;
- First-Look Analysis Tool for Hospital Outlier Monitoring ("FATHOM"), which supports Quality Improvement Organizations in their identification of outlier facilities that require more investigation; and
- Comparative Billing Reports ("CBRs"), which focus on a specific topic/service to determine payment irregularities.

This article focuses on PEPPER reports, which are delivered to operators of many different types of providers, including several post-acute provider types. "PEPPER provides provider-specific Medicare data statistics for discharges/services vulnerable to improper payments. PEPPER can support a hospital or facility’s compliance efforts by identifying where it is an outlier for these risk areas. This data can help identify both potential overpayments as well as potential underpayments." The following types of providers receive PEPPER reports:

- Home Health Agencies
- Skilled Nursing Facilities
- Short-Term Acute Care Hospitals
- Inpatient Psychiatric Facilities
- Hospices
- Inpatient Rehab Facilities
- Partial Hospitalization Programs
- Long-Term Acute Care Hospitals
- Critical Access Hospitals

While the PEPPER program seeks to assist facilities in identifying “potential overpayments as well as potential underpayments,” the value of these reports to investigators must be recognized by the industry. The DOJ, the Department of Health and Human Services’ Office of Inspector General ("OIG"), and other investigating agencies can utilize numerous metrics from the PEPPER reports when analyzing the operations of a facility. The PEPPER reports also compare a facility to the nation, the Medicare Administrative Contractor ("MAC") jurisdiction, and the state.

The PEPPER reports define a set of metrics for each provider type. For each metric, the PEPPER reports identify what may be indicated if a facility were to be considered an outlier. For example, below shows an excerpt from the user’s guide for the SNF PEPPER report. The user’s guide provides suggested interventions if a facility is at/below the 20th percentile or at/above the 80th percentile.

As suggested from the diagram, PEPPER defines outliers as those facilities outside the 20th or 80th percentile of all facilities in the United States. With regards to a metric for which a facility is an outlier, PEPPER indicates that a “provider may wish to review medical record documentation to ensure that services beneficiaries receive are appropriate and necessary and that documentation in the medical record supports the level of care and services for which the SNF received Medicare reimbursement.” Although PEPPER recognizes that an outlier “does not necessarily indicate the presence of improper payment or that the provider is doing anything wrong,” the investigating agency/individual may not appreciate this possibility and may instead interpret the outlier status as support for allegations of improper services or billing. With the analyses and benchmarks available in the PEPPER reports, it is no surprise that investigators are becoming increasingly comfortable relying on these reports as a front-line investigation tool.

Another consideration with respect to information gleaned from PEPPER reports is whether such data implicates the 60-day overpayment rule.

<table>
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<tr>
<th>TARGET AREA</th>
<th>SUGGESTED INTERVENTIONS IF AT/ABOVE 80TH PERCENTILE</th>
<th>SUGGESTED INTERVENTIONS IF AT/BELOW 20TH PERCENTILE</th>
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<tr>
<td>Therapy RUGs with High ADL</td>
<td>This could indicate a risk of potential overcoding of beneficiaries’ activities of daily living (ADL) status. The SNF should determine whether the amount of assistance beneficiaries need with ADL as reported on the MDS is supported and consistent with medical record documentation.</td>
<td>This could indicate a risk of potential undercoding of beneficiaries’ ADL status. The SNF should determine whether the amount of assistance beneficiaries need with ADL as reported on the MDS is supported and consistent with medical record documentation.</td>
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<tr>
<td>Nontherapy RUGs with High ADL</td>
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Section 6402(a) of the Patient Protection and Affordable Care Act established a new section of the Social Security Act requiring a person who has received an overpayment to report and return the overpayment to the Secretary, the state, an intermediary, a carrier, or a contractor, as appropriate, by the later of 60 days from when the overpayment is “identified” or the date any corresponding cost report is due, if applicable. Any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation for purposes of the FCA (a reverse false claim).

In February 2015 CMS published a final rule related to this requirement, applicable to Medicare Part A and Part B healthcare providers and suppliers. Under the final rule, a person has identified an overpayment when the person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. In the final rule, CMS clarified that “reasonable diligence” requires providers and suppliers to undertake ongoing, proactive compliance activities to monitor claims, as well as reactive investigative activities regarding any potential overpayments. Depending on the individual circumstances, data analytics could be one of these ongoing compliance efforts requiring further review and analysis.

Sampling

Another area in which data plays a significant role is in the context of sampling. In FCA investigations, the DOJ or OIG may “draw a sample” or do a “sample review.” The implications of this are significant and providers should understand what this entails. Before discussing these implications, it is helpful to define the word “sampling.”

A provider serves many patients in each time period. These patients are considered the universe. In sampling, an individual develops an approach or sampling plan whereby a certain number of individual patients from the universe are selected and grouped into what is called the sample. A sampling plan can have many different designs and often involves the concept of randomness. The sample is analyzed and conclusions are drawn. Often the DOJ or OIG will want to use the conclusions from their analysis of the sample to make conclusions about the universe. If this is the case, then an individual will complete a process known as extrapolation whereby the sample’s conclusion (e.g., overpayments, error rate) is multiplied to relate to the universe.

The use of sampling has a long-standing history in the administrative context, but was not statutorily authorized until the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”). The MMA established the Medicare Integrity Program, which authorizes Medicare contractors to use extrapolation to determine overpayment amounts when (i) there is a sustained or high level of payment error; or (ii) documented educational intervention has failed to correct the payment error. The Medicare Integrity Program also authorizes a Medicare contractor to request records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

In the context of FCA investigations, government subpoenas or civil investigative demands (“CIDs”) often include requests for medical records associated with specific patients or claims, based on a sample developed by the government or one of its contractors.

In the context of FCA lawsuits, recent court decisions have addressed the legality of sampling as it relates to establishing liability and damages. However, the question is far from settled. The following cases represent recent examples of court decisions involving these issues.

United States ex rel. Martin v. Life Care Centers of America, Inc. (E.D. Tenn.)

The Life Care case was a qui tam action arising from allegations by two former employees against the skilled nursing company; the government intervened in the case before it was settled in October 2016.

The government’s central allegation was that Life Care pressured its therapists to target Ultra High RUG levels and longer ALOS periods for patients to maximize its Medicare revenue. The government contended that as a result of this pressure, Life Care provided therapy that was not medically reasonable or necessary. The government sought to prove its theory based on evidence from statistical sampling and extrapolation of 400 patient admissions and 1,700 claims, representing 54,396 admissions and approximately 154,621 total claims.

Life Care sought partial summary judgment as to the government’s use of statistical sampling and the use of unidentified claims, arguing that the government could not establish falsity (i.e., liability) by extrapolation. The court denied partial summary judgment, finding that “statistical sampling may be used to prove claims brought under the FCA involving Medicare overpayment, but it does not and cannot control the weight that the fact finder may accord to the extrapolated evidence.” In other words, the court decided that determining the weight to afford the extrapolated evidence is best left to a jury. Life Care then filed a motion to certify the summary judgment decision to the Sixth Circuit for interlocutory appeal, which the court denied. Life Care and the government settled the FCA lawsuit with no further rulings regarding the sampling issue.

U.S. ex rel. Michaels et al. v. Agape Senior Community Inc. et al. (4th Cir.)

In United States ex rel. Michaels v. Agape Senior Cmty., Inc., relators
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As these cases show, sampling can have a significant impact on an investigation and/or litigation. A provider, its external counsel, and expert consultants should be involved in all aspects of the sampling to ensure that a fair and reasonable sample is drawn and that any extrapolations are appropriate.

In the sampling approach, aspects to consider include the methodology used to create the sample (e.g., stratification), the representativeness of the sample, the confidence (degree of certainty) levels and the precision (range of accuracy) levels. These aspects will materially affect the size and composition of the sample.

After analyzing the sample, it is important to consider any comparisons that are drawn between the sample and any benchmarks. One must consider the qualitative and quantitative differences among the facility, the sample, and any benchmarks offered.

In challenging the sample, a provider may want to consider conducting an evaluation of the sampling plan, conducting an independent review of the sample claims, conducting a review of non-sample claims (i.e., the universe), and/or challenging the credentials of reviewers analyzing the sample. Should the sample be used in litigation, one may consider Daubert motions as the sampling evidence may be unqualified.

Regardless of whether sampling is used in an investigation or litigation, sampling requires a careful review to ensure that it is being used appropriately. One of the key pitfalls to sampling is the concept of randomness, as many people often equate randomness with representativeness. It is important to remember that pulling a sample randomly does not necessarily mean that the sample will be representative of the universe. Further analysis is needed to ensure that representativeness has been satisfied.

Conclusion

The use of data analytics in the context of healthcare reimbursement and fraud prevention is a key concept. Government contractors have been analyzing data for payment and recovery purposes for the past several years. In the fraud and abuse context, the government and its contractors have also increasingly relied upon available data to identify potential issues for further investigation of wrongdoing by providers. Relators and their counsel have also increasingly mined publicly

(former employees of the Agape nursing home network) initiated a qui tam action claiming damages and other relief under the FCA, the Anti-Kickback Statute, and the Health Care Fraud Statute. The government did not intervene in the case. The relators alleged that Agape submitted false claims to several federal healthcare programs, including Medicare, Medicaid, and TRICARE, seeking reimbursement for nursing home-related services.

The district court rejected the relators’ use of statistical sampling in proving liability and damages, specifically finding that the Agape relators would be required to “prove each and every claim based upon the evidence relating to that particular claim.” The court also noted that statistical sampling would be appropriate when it is the only way for a qui tam relator to prove damages, for example, when evidence has been destroyed or dissipated. The court certified the issue of whether statistical sampling can be used to demonstrate FCA liability without directly analyzing Medicare billing claims, among others, for interlocutory appeal to the Fourth Circuit Court of Appeals. In a February 14, 2017 decision, the Fourth Circuit found that the certification of the statistical sampling ruling for interlocutory review was not appropriate since the question focused on whether the particular methods of statistical sampling used in the Agape matter were reliable, and not the pure legal question of whether sampling is a legally valid technique in determining damages in FCA actions. As such, the issue of whether sampling is an acceptable method to calculate FCA claims or violates due process remains outstanding in the Fourth Circuit and elsewhere.

United States ex rel. Paradies v. AseraCare, Inc. (N.D. Ala.)

United States ex rel. Paradies v. AseraCare Inc. arose out of allegations brought by three relators, in coordination with the government, contending that hospice care provider AseraCare submitted Medicare claims for patients who did not meet the criteria for hospice care. The government sought to establish FCA liability using statistical extrapolation, seeking more than $200 million in damages based on a sample of approximately 120 patients.

The court initially denied AseraCare’s motion for summary judgment, concluding that “statistical evidence is evidence” of falsity to defeat summary judgment. The trial was then bifurcated into falsity and scienter phases. Following the first phase (falsity), the judge granted a new trial based on error in instructing the jury: failing to provide complete instructions as to what was legally necessary for the jury to find that the claims before it were false. In March 2016, the court granted summary judgment to AseraCare based on the government’s failure to prove falsity, explaining that mere differences in clinical judgment are not enough to establish FCA falsity, and the government had not produced evidence other than conflicting medical expert opinions. The government has appealed to the Eleventh Circuit Court of Appeals.

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Conclusion

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available claims data in bringing FCA qui tam actions.

What has changed is the government’s increasing reliance on data to develop theories of wrongdoing by providers. As a result, it is imperative that providers are well-aware of their own data, and the optics of such data, particularly as it compares to the data of other, similar providers, which is available through public sources. Providers should be proactively monitoring their own data as it relates to the relevant data elements discussed above. Proactive monitoring requires not only an awareness of the actual data metrics, but also an understanding of and appreciation for the factors that contribute to, or influence, the metrics. Knowing this information will allow a provider to quickly and intelligently respond to a government investigation, if necessary. Further, in the context of government investigations, data analytics can be used by providers to contradict, or put into more accurate context, government allegations of wrongdoing, to resolve an investigation, to assist in settlement negotiations, or to dissuade the government from intervening in a qui tam case.

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Endnotes
1 Many healthcare fraud investigations are premised on alleged violations of the FCA, which prohibits committing or conspiring to commit certain fraudulent activities, including knowingly presenting (or causing to be presented) a false claim for payment or approval by a federal healthcare program; knowingly making, using (or causing) a false record or statement to get a false claim paid/approved; and knowingly concealing or improperly avoiding/decreasing a government obligation (a reverse false claim). 31 U.S.C. § 3729 et seq. In addition to the federal FCA, there are a variety of other federal and state statutes that address Medicare and Medicaid fraud, including 18 U.S.C. § 1001 (the False Statements Act); 18 U.S.C. §§ 1341, 1343 (federal mail and wire fraud); and various state false claims laws.
2 The Medicare program reimburses each type of provider using a different methodology. As such, there are different key data elements of interest for each type of provider, which may be considered in the context of a government investigation. For each provider these data elements need to be viewed in concert with one another, as one metric is often affected by another metric.
3 Medicare Part A relates to coverage provided to Medicare beneficiaries for hospital, SNF, home health, and hospice care. In contrast, Medicare Part B covers, among other things, doctor’s services, hospital outpatient services, and laboratory tests.
4 For additional information regarding assessment of residents, see https://cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/SNFFPSAssessment.pdf.
5 Medicare defines a change of therapy assessment as when a provider must assess a patient if the amount of therapy provided to a patient changes to the extent that a patient’s RUG would also shift from the RUG assigned to the patient’s last assessment.
6 For more information, see MedPAC Payment Basics for Inpatient Rehabilitation Facilities: http://medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_16_if_final.pdf?sfvrsn=0.
8 For more information, see MedPAC Payment Basics for Hospice Services: http://medpac.gov/docs/default-source/payment-basics/hospice-services-payment-system-15.pdf?sfvrsn=0.
9 OASIS is a data set run by CMS in conjunction with home health providers. More information on OASIS can be found at https://cms.gov/Medicare/Quality-ImprovementOrgs/OASIS/Background.html.
11 116 STAT. 2350.
12 124 STAT. 2224.
13 126 STAT. 2390.
14 The QIO Program, “one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries, is an integral part of the U.S. Department of Health and Human (HHS) Services’ National Quality Strategy for providing better care and better health at lower cost.” More information can be found at: https://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/qualityimprovementorgs.
15 See PEPPER Resources, the official site for information, training and support related to PEPPER, available at https://pepperresources.org.
16 “A Medicare Administrative Contractor (MAC) is a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B (A/B) medical claims or Durable Medical Equipment (DME) claims for Medicare Fee-For-Service (FFS) beneficiaries.” MACs process all Medicare FFS claims for a given geographic area. More information on MACs can be found at https://cms.gov/medicare/medicare-contracting/mac-medicare-administrative-contractors/what-is-a-mac.html.
17 The PEPPER user’s guide is available at https://pepperresources.org.
19 Id.
20 42 U.S.C. § 1320a-7(d).
21 Id.
23 42 C.F.R. § 401.305(a)(2).
25 See, e.g., 42 C.F.R. § 405.1264 (ALJ decisions involving statistical samples); Section III.B of the OIG’s Provider Self Disclosure Protocol (requiring a provider’s overpayment calculation to “consist of a review of either: (1) all the claims affected by the disclosed matter or (2) a statistically valid random sample of the claims that can be projected to the population of claims affected by the matter”); HCFA Ruling 86-1 (Hospital Insurance and Supplementary Medical Insurance Benefits (Parts A and B) Use of Statistical Sampling to Project Overpayments to Providers and Suppliers).

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From a practical standpoint, subpoenas and CIDs operate in a similar fashion: they allow the government to request certain documents. However, a CID goes further than a subpoena because it can require the recipient to not only produce documents, but to also answer interrogatories and give oral testimony under oath. 31 U.S.C. § 3733(a). CIDs have become increasingly more common since all U.S. Attorneys can now issue CIDs. Prior to 2010, only the Attorney General was authorized to issue a CID and that authority could not be delegated. However, the Fraud Enforcement and Recovery Act (2009) authorized the Attorney General to delegate that authority to others within the DOJ.


United States ex rel. Michaels v. Agape Senior Cmty., Inc., 2015 WL 3903675 (D.S.C. June 25, 2015). The federal Anti-Kickback Statute and its implementing regulations make it a criminal offense to knowingly or willfully offer, pay, solicit or receive any remuneration in exchange for, or to induce, referring an individual to another person or entity for the furnishing, or arranging for or recommending the purchase, of any item or service that may be paid for in whole or in part by a federal healthcare program, including Medicare and Medicaid. 42 U.S.C. § 1320a-7b(h). The Health Care Fraud Statute makes it a criminal offense to knowingly and willfully execute a scheme to defraud a healthcare benefit program. 18 U.S.C. Code § 1347.

United States ex rel. Michaels v. Agape Senior Cmty., Inc., No. 15-238 (L) (E.D. Tenn. Sept. 29, 2015). The district court also certified for interlocutory appeal the issue of whether the DOJ has absolute veto power over FCA settlements in cases where it has not intervened. The DOJ blocked settlement of the proposed settlement amount was too low and proposed release of legal liability too broad.

United States ex rel. Michaels v. Agape Senior Community, et al., 2017 WL 588356 (4th Cir. 2017). With respect to the issue of veto power, the Fourth Circuit held that the government has an absolute veto power over voluntary settlements in FCA matters even when it declines to intervene in the case.


A Daubert motion, named after a Supreme Court case, Daubert v. Merrell Dow Pharms., 509 U.S. 579 (U.S. 1993), is a specific type of motion in limine used to exclude the presentation of unqualified evidence to the jury.
21st CENTURY CURES ACT: A MYRIAD OF HEALTH LAW REMEDIES

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In December 2016, President Barrack Obama signed the 21st Century Cures Act ("Cures Act"). Unlike the Patient Protection and Affordable Care Act ("PPACA"), the Cures Act was passed by Congress with a large amount of bipartisan support. The law passed the House with a vote of 392 to 26 and passed the Senate with a vote of 94 to 5.

One of the main goals of this law is to fund biomedical research and speed the approval of new drugs and medical devices. This is a positive legislative action to reposition the United States in the pharmaceutical and biomedical industry, and has received the most media attention. However, the law is much more comprehensive and addresses many other aspects of healthcare. This legislation also addresses helping families in mental health crisis and contains significant provisions related to behavioral health. It contains provisions for increasing choice, access and quality in healthcare for Americans and includes provisions related to child and family services support.

The Title 21st Century Cures Act accurately describes the first part of this legislation, but the other three parts could separately be named the "Mental Health Crisis Act," the "Choice, Access & Quality Care Act," and the "Child & Family Services Support Act." It is surprising that there has not been more media attention on the part of this legislation that addresses the mental health crisis in America. Furthermore, many of the themes in the third section related to increasing choice, access and quality in healthcare are themes that were also addressed in PPACA.

The Cures Act is divided into 25 titles – five in Division A – 21st Century Cures, nine in Division B – Helping Families in Mental Health Crisis, four in Division C – Increasing Choice, Access, and Quality in Health Care for Americans, and seven titles in Division D – Child and Family Services Support. Congressional funding for this legislation totals $6.3 billion. The titles address a myriad of disparate issues, ranging from development of medical devices and fighting opioid addiction to clarifying the Health Information Portability and Accountability Act ("HIPAA"), improving legal guardianship requirements, and restricting health information technology information blocking. This article provides a summary and roadmap of what is contained in each of the titles of the Cures Act.

Division A – 21st Century Cures

Title I – Innovation Projects and State Responses to Opioid Use

Title I covers both innovation projects and state responses to opioid use. Both National Institutes of Health ("NIH") and Food and Drug Administration ("FDA") innovation projects are included. This title contains funding amounts to be transferred from the general treasury fund for the NIH’s Precision Medicine Initiative, the Brain Through Advancing Innovative Neuro-technologies Initiative ("Brain Initiative") to support cancer research, and for adult stem cell research. It also provides funding so that the FDA can move drugs and medical devices more quickly through the approval process. According to President Obama, the Cures Act:

[...]invests nearly $3 billion to build upon the major biomedical research initiatives...known as the BRAIN and Precision Medicine Initiatives which are tackling diseases like Alzheimer’s and creating new research models to find cures and better target treatments. We are now one step closer to ending cancer as we know it, unlocking cures for diseases like Alzheimer’s, and helping people seeking treatment for opioid addiction finally get the help they need.... The bipartisan passage of the 21st Century Cures Act is an example of the progress we can make when people from both parties work together to improve the health of our families, friends and neighbors...."

The Cures Act also provides funding to help states respond to the opioid use crisis for, among other things, improving prescription drug monitoring programs, increasing provider training, and improving access to opioid treatment programs. The Cures Act “includes $500 million a year to help states prevent opioid misuse and get better treatment for addicts.”

Title II – Discovery

This title focuses on funding for research in science and medicine, and has been called “one of the most important features of the law.” It is divided into seven subtitles: (A) National Institutes of Health Reauthorization, (B) Advancing Precision Medicine, (C) Supporting Young Emerging Scientists, (D) National Institutes of Health Planning and Administration, (E) Advancement of the National Institute of Health Research and Data Access, (F) Facilitating Collaborative Research, and (G) Promoting Pediatric Research. Among other things, the law creates a “Next Generation of Researchers Initiative,” encouraging the Secretary of the Department of Health and Human Services (“HHS”) to coordinate with

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other agencies in advancing precision medicine, and supports continued global pediatric research.

Under the Precision Medicine Initiative, the Secretary of HHS may: (1) in part, coordinate with private industry to address the advanced supercomputing and other advanced technology needs of the Initiative, (2) develop and utilize public-private partnerships and (3) leverage existing data sources.5 Precision Medicine provides potential cures for numerous illnesses such as cancer by targeting the diseases at the molecular level. The mapping of the human genome has created very exciting scientific breakthroughs that are very promising. This law aims to accelerate such research and re-position the United States to again be the dominant leader in this industry.

Title III – Development

Title III covers the development of drugs and medical devices and is divided into the following ten subtitles: (A) Patient-Focused Drug Development, (B) Advancing New Drug Therapies, (C) Modern Trial Design and Evidence Development, (D) Patient Access to Therapies and Information, (E) Antimicrobial Innovation and Stewardship, (F) Medical Device Innovations, (G) Improving Scientific Expertise and Outreach at the FDA, (H) Medical Countermeasures Innovation, (I) Vaccine Access, Certainty and Innovation, and (J) Technical Corrections. For instance, it allows the FDA to grant accelerated approvals for drugs and devices in certain instances, requires the FDA to use guidance to collect patient experience data, and provides the agency with the flexibility to waive or alter informed consent requests for clinical trials.

The section on medical device innovations contains an expedited process for the approval of medical devices that are designated as breakthrough technologies. The purpose of the section is to provide the Secretary of HHS with flexible approaches to expedite FDA approval of such devices. The statute mandates that one year after the enactment of the Cures Act the Secretary of HHS will provide guidance as to the process for designation as a breakthrough technology.9

Title IV – Delivery

Title IV Delivery addresses the following topics: (1) assisting doctors and hospitals in improving quality of care for patients, (2) transparent reporting on usability, security and functionality, (3) interoperability, (4) information blocking, (5) leveraging electronic health records to improve patient care, (6) empowering patients and improving patient access to their electronic health information, (7) mandating that within one year of the enactment of the Cures Act the Comptroller General shall submit to Congress a Government Accountability Office (“GAO”) study on patient matching, (8) requiring the Comptroller General to build on prior GAO studies and conduct a study on patient access to health information, (9) streamlining transfers used for educational purposes, (10) improving Medicare local coverage determinations, (11) requiring the Secretary of HHS to provide for a pharmaceutical and technology ombudsman within CMS, (12) Medicare site-of-service price transparency, and (13) telehealth services in Medicare.

This title contains significant provisions related to health information technology. “Some of the core health IT components of the legislation as read in Title IV – Delivery section of the law, include encouraging interoperability of electronic health records (EHRs) and patient access to health data, discouraging information blocking, reducing physician documentation burden, as well as creating a reporting system on EHR usability... Drilling down, the interoperability and information blocking components of the legislation have seemed to garner the most buzz so far.”10

It also contains new definitions for “interoperability” and “information blocking”. Section 4003 defines “interoperability” as:

The term ‘interoperability’, with respect to health information technology, means such health information technology that—

(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

(C) does not constitute information blocking as defined in section 3022(a).

Section 3022(a) defines “information blocking” as:

(1) In this section, the term ‘information blocking’ means a practice that—

(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

(B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

(ii) if conducted by a health care
provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

(2) PRACTICES DESCRIBED.
– The information blocking practices described in paragraph (1) may include “(A) practices that restrict authorized access, exchange, or use under applicable State or Federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies;

(B) implementing health information technology in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information; and

(C) implementing health information technology in ways that are likely to – (i) restrict the access, exchange, or use of electronic health information with respect to exporting complete information sets or in transitioning between health information technology systems; or (ii) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health information technology.

Section 3022(b)(2) of the Cures Act contains penalty provisions to prohibit such information blocking. Section 3022(b)(2) states:

Developers, Networks & Exchanges...that the [HHS] Inspector General...determines to have committed information blocking shall be subject to a civil monetary penalty determined by the Secretary for all such violations which may not exceed $1,000,000 per violation. Such determination shall consider factors such as the nature and extent of the information blocking and harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected and the number of days the information blocking persisted.

These provisions of the Cures Act related to “interoperability” and “information blocking” are quite significant. While interoperability of electronic health records creates significant benefits, the privacy and security of the underlying medical information could become a concern, especially if the data is not properly secured from improper disclosures.

Title V – Savings

The Cures Act contains a savings section that includes the following sections: (1) savings in the Medicare Improvement Fund, (2) Medicaid reimbursement to states for durable medical equipment, (3) penalties for violations of grants, contracts, and other agreements, (4) reducing overpayments of infusion drugs, (5) increasing oversight of termination of Medicaid providers, (6) requiring publication of a fee-for-services provider directory, (7) fairness in Medicaid supplemental needs trusts, (8) eliminating federal financial participation with respect to expenditures under Medicaid for agents used for cosmetic purposes or hair growth, (9) amendment to the prevention and public health fund, (10) a strategic petroleum reserve drawdown, (11) a rescission of a portion of PPACA territory funding, and (12) Medicare coverage of home infusion therapy.

Among other things, this title also amends section 1128 A of the Social Security Act to add the following:

(o) Any person (including an organization, agency, or other entity, but excluding a program beneficiary, as defined in subsection (q)(4)) that, with respect to a grant, contract, or other agreement for which the Secretary provides funding—

(1) knowingly presents or causes to be presented a specified claim (as defined in subsection (r)) under such grant, contract, or other agreement that the person knows or should know is false or fraudulent;

(2) knowingly makes, uses, or causes to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document that is required to be submitted to directly or indirectly receive or retain funds provided in whole or in part by such Secretary pursuant to such grant, contract, or other agreement;

(3) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent specified claim under such grant, contract, or other agreement;

(4) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation (as defined in subsection (s)) to pay or transmit funds or property to such Secretary with respect to such grant, contract or other agreement, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement; or

(5) fails to grant timely access, upon reasonable request (as defined by such Secretary in regulations), to the Inspector General of the Department, for the purpose of audits, investigations, evaluations, or other statutory functions of such Inspector General in matters involving such grants, contracts, or other agreements; shall be subject, in addition to any other penalties that may be prescribed by law, to a continued on page 34
Division B – Helping Families in Mental Health Crisis

Title VI – Strengthening Leadership and Accountability

This title is divided into three subtitles: (A) Leadership, (B) Oversight and Accountability, and (C) Interdepartmental Serious Mental Illness Coordinating Committee. The law creates a new position in the Executive branch for an Assistant Secretary for Mental Health and Substance Abuse. It also has sections for: strengthening the leadership of the Substance Abuse and Mental Health Services Administration (section 6002), having the Assistant Secretary of HHS with the approval of the Secretary of HHS Services appoint a Chief Medical Officer (section 6003), improving the quality of behavioral health programs (section 6004), developing a strategic plan (section 6005), creating a biennial report by the Secretary of HHS for Congress concerning activities and progress (section 6006), providing authorities to assess the effectiveness of grants related to the Centers for Mental Health Services and substance abuse prevention and substance abuse treatment (section 6007), developing advisory councils (section 6008), and amending peer review provisions to address peer review of grants related to mental health (section 6009).

Subtitle B, related to oversight and accountability, contains sections for: (1) improving oversight of mental and substance abuse disorders programs through the Assistant Secretary for Planning and Evaluation, (2) reporting for protection and advocacy organizations, and (3) requiring that the Comptroller General prepare a GAO study to submit to Congress that establishes an interdepartmental serious mental illness coordinating committee.

Section 14026 related to the GAO report requires the Comptroller General in coordination with the Attorney General to submit to Congress a report on:

1. The practices that federal first responders tactical units and corrections officers are trained to use in responding to individuals with mental illness;
2. Procedures to identify and appropriately respond to incidents which the unique needs of individuals who have mental illness are involved to federal first responders and tactical units;
3. The application of evidenced based practices in criminal justice settings to better address individuals with mental illnesses; and
4. Recommendations on how the Department of Justice (“DOJ”) can expand and improve information sharing and dissemination of best practices.

Title VII – Ensuring Mental and Substance Abuse Use Disorders Prevention, Treatment and Recovery Programs Keep Pace with Science and Technology

This title is designed to ensure that mental health and substance use disorder prevention, treatment and recovery programs keep pace with technology. It is divided into five sections: (1) encouraging innovation and evidence-based programs, (2) promoting access to information on evidence-based programs and practices, (3) mental health needs of regional and national significance that are a priority as determined by HHS, (4) priority substance abuse order treatment needs of regional and national significance, and (5) priority substance abuse order prevention needs of regional and national significance.

Title VIII – Supporting State Prevention Activities and Responses to Mental Health and Substance Use Disorder Needs

A key component of this title is for the federal government to provide block grants to the states to augment their efforts in preventing and treating substance abuse disorders. Section 8001 addresses the community mental health services block grant; section 8002 discusses the substance abuse prevention and treatment block grant; and section 8003 contains additional provisions related to these two block grants. Section 8004 provides for the study of the distribution of funds under the substance abuse prevention and treatment block grant and the community mental health services block grant.
Title IX – Promoting Access to Mental Health Substance Use Disorder Care

This title has three subtitles related to promoting access to mental health substance use disorder care: Subtitle A – Helping Individuals and Families, Subtitle B – Strengthening the Health Care Workforce, and Subtitle C – Mental Health on Campus Improvement. For instance, it provides education to providers and on college campuses, provides grant money for treatment of the homeless, and requires HHS to continue the National Suicide Prevention Lifeline Program.

Title X – Strengthening Mental and Substance Use Disorder Care for Children and Adolescents

Title X strengthens mental and substance use disorder care for children and adolescents. This title addresses: (1) programs for children with a serious emotional disturbance, (2) increasing access to pediatric mental health care, (3) substance abuse disorder treatment and earlier intervention services for children and adolescents, (4) children’s recovery from trauma, (5) screening and treatment for maternal depression, and (6) infant and early childhood mental health promotion, intervention and treatment. Among other things, this title contains provisions regarding state grants. Specifically, the Secretary, acting through the Administrator of the Health Resources and Services Administration and in coordination with other relevant federal agencies, shall award grants to states, political subdivisions of states, and Indian tribes and tribal organizations (for purposes of this section, as such terms are defined in section four of the Indian Self-Determination and Education Assistance Act (25 U.S.C. § 450b)) to promote behavioral health integration in pediatric primary care by:

1. supporting the development of statewide or regional pediatric mental healthcare telehealth access programs; and

2. supporting the improvement of existing statewide or regional pediatric mental healthcare telehealth access programs.

Title XI – Compassionate Communication on HIPAA

This title discusses: (1) sense of Congress, (2) confidentiality of records, (3) clarification on permitted uses and disclosures of protected health information, and (4) development and dissemination of model training programs. It is the sense of Congress that clarification is needed regarding the privacy rule promulgated under section 264(c) of HIPAA (42 U.S.C. § 1320d–2 note) regarding existing permitted uses and disclosures of health information by healthcare professionals to communicate with caregivers of adults with a serious mental illness to facilitate treatment. Not later than one year after the date on which the Secretary of HHS first finalizes regulations updating part 2 of title 42, Code of Federal Regulations, relating to the confidentiality of alcohol and drug abuse patient records, the Secretary shall convene relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy.

The Secretary, acting through the Director of the Office for Civil Rights, shall ensure that healthcare providers, professionals, patients and their families, and others involved in mental or substance use disorder treatment have adequate, accessible, and easily comprehensible resources relating to appropriate uses and disclosures of protected health information under the regulations promulgated under section 264(c) of HIPAA (42 U.S.C. § 1320d–2 note).

Furthermore, not later than one year after the date of enactment of this section, the Secretary shall issue guidance clarifying the circumstances under which, consistent with regulations promulgated under section 264(c) of HIPAA, a healthcare provider or covered entity may use or disclose protected health information. The guidance issued under this section shall address circumstances including those that:

A. require the consent of the patient;
B. require providing the patient with an opportunity to object;
C. are based on the exercise of professional judgment regarding whether the patient would object when the opportunity to object cannot practically be provided because of the incapacity of the patient or an emergency treatment circumstance; and
D. are determined, based on the exercise of professional judgment, to be in the best interest of the patient when the patient is not present or otherwise incapacitated.

The guidance issued under this section shall clarify permitted uses or disclosures of protected health information for purposes of:

A. communicating with a family member of the patient, caregiver of the patient, or other individual, to the extent that such family member, caregiver, or individual is involved in the care of the patient;
B. in the case that the patient is an adult, communicating with a family member of the patient, caregiver of the patient, or other individual involved in the care of the patient;
C. in the case that the patient is a minor, communicating with the parent or caregiver of the patient;
D. involving the family members or caregivers of the patient, or others involved in the patient’s care or care plan, including facilitating treatment and medication adherence;
E. listening to the patient, or receiving information with respect to the patient from the family or caregiver of the patient;

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(F) communicating with family members of the patient, caregivers of the patient, law enforcement, or others when the patient presents a serious and imminent threat of harm to self or others; and

(G) communicating to law enforcement and family members or caregivers of the patient about the admission of the patient to receive care at, or the release of a patient from, a facility for an emergency psychiatric hold or involuntary treatment.

Title XII – Medicaid Mental Health Coverage

For Medicaid mental health coverage, this legislation provides for: (1) a rule of construction related to Medicaid coverage of mental health services and primary care services furnished on the same day, (2) study and report related to Medicaid managed care regulation, (3) guidance on opportunities for innovation, (4) study and report on a Medicaid emergency psychiatric demonstration project, (5) early and periodic screening, diagnostic, and treatment services (“EPSDT”) to children in institutions for mental disease (“IMDs”), and (6) a new electronic visit verification system for personal care services and home healthcare services under Medicaid.

Unless a state requires the use of an electronic visit verification system for such services furnished under the plan or such waiver, it will incur a penalty in the form of less Medicaid funding. The federal medical assistance percentage shall be reduced—

(A) in the case of personal care services—

(i) for calendar quarters in 2019 and 2020, by .25 percentage points;

(ii) for calendar quarters in 2021, by .5 percentage points;

(iii) for calendar quarters in 2022, by .75 percentage points; and

(iv) for calendar quarters in 2023 and each year thereafter, by 1 percentage point; and

(B) in the case of home health care services—

(i) for calendar quarters in 2023 and 2024, by .25 percentage points;

(ii) for calendar quarters in 2025, by .5 percentage points;

(iii) for calendar quarters in 2026, by .75 percentage points; and

(iv) for calendar quarters in 2027 and each year thereafter, by 1 percentage point.

Title XIII – Mental Health Parity

Mental health parity, a topic that was also addressed in PPACA, is contained in this new legislation. This title contains parity provisions that address: (1) enhanced compliance with mental health and substance abuse disorder coverage requirements, (2) an action plan for enhanced enforcement of mental health and substance use disorder benefits, (3) a report on investigations regarding parity in mental health and substance abuse disorder coverage, (4) a GAO study on parity in mental health and substance abuse disorder benefits, (5) information and awareness on eating disorders, (6) education and training on eating disorders, and (7) clarification of existing parity rules.

Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016 (which is Division B of the Cures Act), the Secretary of HHS, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of HHS, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury shall issue a compliance program guidance document to help improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, and section 9812 of the Internal Revenue Code of 1986, as applicable.

Title XIV – Mental Health and Safe Communities

The Cures Act contains provisions related to mental health and safe communities. With all that has been seen in the press about violence, it is surprising that this portion of the legislation has not received more attention by the mainstream media. This title contains two subtitles: (A) mental health and safe communities and (B) comprehensive justice and mental health.

Subtitle A contains sections related to: (1) law enforcement grants for crisis intervention teams and mental health purposes, (2) assisted outpatient treatment programs, (3) federal drug and mental health courts, (4) mental health and the judicial system, (5) forensic assertive community treatment initiatives, (6) assistance for individuals transitioning out of systems, (7) co-occurring substance abuse and mental health challenges in drug courts, (8) mental health training for uniformed services, (9) advancing mental health as part of offender re-entry, (10) school mental health crisis intervention teams, (11) active shooter training for law enforcement, (12) co-occurring substance abuse and mental health challenges in residential substance abuse treatment programs, (13) mental health and drug treatment alternatives to incarceration programs, and (14) national criminal justice and mental health training and technical assistance.

Subtitle B on comprehensive justice and mental health contains provisions for: (1) a sequential intercept model, (2) prisons and jails, (3) allowable uses, (4) law enforcement training,
Among other things, this title creates a pilot program establishing a drug and mental health court to be established no later than one year after the date that the Cures Act is enacted. The pilot program will determine the effectiveness of diverting eligible offenders from federal prosecution, federal probation, or a Bureau of Prisons facility, and placing such eligible offenders in drug or mental health courts.

The pilot program shall involve:

(1) continuing judicial supervision, including periodic review, of program participants who have a substance abuse problem or mental illness; and

(2) the integrated administration of services and sanctions, which shall include:

(A) mandatory periodic testing, as appropriate, for the use of controlled substances or other addictive substances during any period of supervised release or probation for each program participant;

(B) substance abuse treatment for each program participant who requires such services;

(C) diversion, probation, or other supervised release with the possibility of prosecution, confinement, or incarceration based on noncompliance with program requirements or failure to show satisfactory progress toward completing program requirements;

(D) programmatic offender management, including case management, and aftercare services, such as relapse prevention, healthcare, education, vocational training, job placement, housing placement, and child care or other family support services for each program participant who requires such services;

(E) outpatient or inpatient mental health treatment, as ordered by the court, that carries with it the possibility of dismissal of charges or reduced sentencing upon successful completion of such treatment;

(F) centralized case management, including:

(i) the consolidation of all cases, including violations of probation, of the program participant; and

(ii) coordination of all mental health treatment plans and social services, including life skills and vocational training, housing and job placement, education, healthcare, and relapse prevention for each program participant who requires such services; and

(G) continuing supervision of treatment plan compliance by the program participant for a term not to exceed the maximum allowable sentence or probation period for the charged or relevant offense and, to the extent practicable, continuity of psychiatric care at the end of the supervised period.

Division C – Increasing Choice, Access, and Quality in Healthcare for Americans

Title XV – Provisions Related to Medicare Part A

The Cures Act contains provisions related to Medicare Part A in the following categories: (1) development of Medicare HCPCS versions of MS–DRG codes for similar hospital services, (2) establishing beneficiary equity in the Medicare hospital readmission program, (3) a five-year extension of the rural community hospital demonstration program, (4) regulatory relief for long term care hospitals (“LTCHs”), (5) savings from the inpatient prospective payment system (“IPPS”) MACRA (the Medicare Quality Payment Program) pay-for through not applying documentation and coding adjustments, (6) extension of certain LTCH Medicare payment rules, (7) application of rules on the calculation of hospital length of stay to all LTCHs, (8) change in Medicare classification for certain hospitals, (9) creation of an exception to the application of the Medicare LTCH site neutral provisions for certain spinal cord specialty hospitals, and (10) a temporary extension to the application of the Medicare LTCH site neutral provisions for certain discharges of patients with severe wounds.

Included in this title is the provision that the Comptroller General of the United States shall, in consultation with relevant stakeholders, conduct a study on the treatment needs of individuals entitled to benefits under Medicare Part A or Part B who require specialized wound care, and the cost for such individuals and the Medicare program of treating severe wounds in rural and urban areas.

Title XVI – Provisions Related to Medicare Part B

The Cures Act contains provisions related to Medicare Part B in the following categories: (1) continuing Medicare payment under the hospital outpatient department (“HOPD”) prospective payment system for services furnished by mid-build off-campus outpatient departments of providers, (2) treatment of cancer hospitals in off-campus outpatient departments of providers, (3) treatment of eligible professionals in ambulatory surgical centers for meaningful use and the Merit-based Incentive Payment System (“MIPS”), (4) Continuing Access to Hospitals Act of 2016, (5) delay of implementation of Medicare fee schedule adjustments for wheelchair accessories and seating systems when used in conjunction with complex rehabilitation technology (“CRT”) wheelchairs, (6) allowing physical therapists to utilize locum
tenens arrangements under Medicare, (7) extension of the transition to new payment rates for durable medical equipment under the Medicare program, and (8) requirements in determining adjustments using information from competitive bidding programs.

Title XVII – Other Medicare Provisions

The Cures Act contains additional Medicare provisions related to the following: (1) it delays the Secretary of HHS' authority to terminate contracts for Medicare Advantage plans failing to achieve minimum quality ratings, (2) the requirement for enrollment data reporting for Medicare, (3) updating the Welcome to Medicare package, (4) no payment for items and services furnished by newly enrolled providers or suppliers within a temporary moratorium area, (5) preservation of Medicare beneficiary choice under Medicare Advantage, (6) allowing end-stage renal disease beneficiaries to choose a Medicare Advantage plan, and (7) improvements to the assignment of beneficiaries under the Medicare Shared Savings Program. For instance, the Welcome to Medicare package needs to include information, presented in a clear and simple manner, about the different options for receiving benefits under the Medicare program.

Title XVIII – Other Provisions

Title XVIII contains an exception from group health plan requirements for qualified small employer health reimbursement arrangements.

Division D – Child and Family Services and Support

Title XIX – Investing in Prevention and Family Services

Title XIX of the Cures Act contains provisions related to: (1) foster care and prevention services and programs, (2) foster care maintenance payments for children with parents in a licensed residential family-based treatment facility for substance abuse, (3) payments for evidence-based kinship navigator programs, (4) eliminating time limits for family reunification services while in foster care and permitting time-limited family reunification services when a child returns home from foster care, (5) reduction of bureaucracy and unnecessary delays when placing children in homes across state lines, (6) enhancements to grants to improve the well-being of families affected by substance abuse, and (7) reviewing and improving licensing standards for placement in a relative foster family home and development of a statewide plan to prevent child abuse and neglect fatalities.

Title XX – Ensuring the Necessity of a Placement that is Not in a Foster Home

Title XX contains the following provisions related to ensuring the necessity of a placement that is not in a foster home: (1) limitation on federal financial participation for placements that are not in foster family homes, (2) assessment and documentation of the need for placement in a qualified residential treatment program, (3) protocols to prevent inappropriate diagnoses, and (4) additional data and reports regarding children placed in a setting that is not a foster family home.

Title XXI – Continuing Support for Child and Family Services

This title addresses the continuing support for child and family services: (1) supporting and retaining foster families for children, (2) extending child and family services programs, and (3) improvements to the John H. Chafee foster care independence program and related provisions.

Title XXII – Continuing Incentives to States to Promote Adoption and Legal Guardianship

Title XXII provides continuing incentives to states to promote adoption and legal guardianship. It specifically includes a section reauthorizing adoption and legal guardianship incentive programs.

Title XXIII – Technical Corrections

Title XXIII contains technical corrections to data exchange standards to improve program coordination and to state requirements to address the developmental needs of young children.

Title XXIV – Ensuring States Reinvest Savings Resulting from Increase in Adoption Assistance

This title includes provisions for ensuring that states reinvest savings resulting from increases in adoption assistance. Specifically, it contains provisions for the: (1) delay of adoption assistance phase-in and a GAO study and report on state reinvestment of savings resulting from increases in adoption assistance.

Title XXV – Social Impact Partnerships to Pay for Results

Section 403 of the Social Security Act (42 U.S.C. § 603) is amended to add social impact demonstration projects. The purposes of these projects are the following:

(A) To improve the lives of families and individuals in need by funding social programs that achieve real results;
(B) To redirect funds away from programs that, based on objective data, are ineffective, and into programs that achieve demonstrable, measurable results;
(C) To ensure that federal funds are used effectively on social
services to produce positive outcomes for both service recipients and taxpayers; 

(D) To establish the use of social impact partnerships to address some of the Nation’s most pressing problems; 

(E) To facilitate the creation of public/private partnerships that bundle philanthropic or other private resources with existing public spending to scale up effective social interventions already being implemented by private organizations, nonprofits, charitable organizations, and state and local governments across the country; 

(F) To bring pay-for-performance to the social sector, allowing the United States to improve the impact and effectiveness of vital social services programs while redirecting inefficient or duplicative spending; 

(G) To incorporate outcomes measurement and randomized controlled trials or other rigorous methodologies for assessing program impact. 

Title XXV can be cited as the “Social Impact Partnership to Pay for Results Act.” Among other things it strengthens welfare research and evaluation, and the development of a “what works” clearinghouse.

Conclusion 

The Cures Act is a very comprehensive new bipartisan healthcare law that contains not only provisions related to enhancing research for medical cures, but for solving the mental health crisis; increasing choice, access and quality in healthcare; and addressing child and family services support. While it is not yet known how the new Administration will address the provisions, the fact that the Cures Act was so bipartisan may indicate that its provisions will not be set aside or put on the chopping block. Indeed, the section increasing choice, access and quality, which mirrors provisions in PPACA, may serve to preserve those concepts in the event that PPACA is repealed.

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Endnotes 

4 Id. 
5 Quote by President Barack Obama in NBC news article dated December 7, 2016, “Senate Passes Sweeping 21st Century Cures Act Funding Medicine.” 
6 Quote by Agriculture Secretary Tom Vilsack, in NBC news article dated December 7, 2016, “Senate Passes Sweeping 21st Century Cures Act Funding Medicine.” 
7 In particular, the law provides for more than $6 billion in funding for the National Institutes of Health (NIH). Fox News Health “How the 21st Century Cures Act will save lives through research,” January 24, 2017. 
8 Cures Act Section 498E(c). 
9 Cures Act Section 515C. 
SECTION CALENDAR

For more information on any of these programs, call the Section at 312/988-5532 or visit the Section website at www.americanbar.org/health

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