BURR ARTICLE

2016 Health Care Year in Review

Reprinted with Permission from the ***Birmingham Medical News***

by Howard E. Bogard
December 9, 2016

Since I began writing this year-end review in 2013, there have been some common themes - a shift to pay for quality and away from fee-for-service, much of which has been brought about by the Affordable Care Act (ACA): efforts to combat fraud and abuse in the health care system; provider consolidation; Alabama Medicaid's ongoing struggle to cover the cost of health care for our most needy citizens; and increased regulations for the health care industry.

2016 has been no different, but with the election of Donald Trump, change is definitely coming. With Congress under Republican control, a full (or at least a meaningful) repeal of the ACA is expected. We can also anticipate Medicaid and insurance reform.

I have a feeling that my 2017 year-end review will be very interesting. For now, however, the following are my top ten 2016 health care events for Alabama providers.

10. **Hospital Payment Reforms Continue**. In 2016 we continued to see CMS pursue various incentive programs for hospitals, all designed to move at least 50 percent of Medicare payments to quality or value-based programs by 2018. CMS launched a series of pilot programs through its Bundled Payment for Care Improvement initiative, including bundled payments in the areas of oncology, joint replacement and cardiac care. A bundled payment combines multiple services into a single payment to providers for a defined condition or course of treatment including follow-up services, also known as an episode of care. Other payment reform programs include the Hospital Value-Based Purchasing Program, which rewards acute care hospitals with incentive payments for the quality of care they provide to Medicare beneficiaries. Another program, the Hospital Readmission Reduction Program, provides financial incentives to hospitals to reduce unnecessary hospital readmissions.

9. **Fraud and Abuse Initiatives**. According to the HHS Office of Inspector General (OIG) Semiannual Report to Congress, from October 1, 2015 to March 31, 2016, fraud and abuse recoveries exceeded $2.77 billion, which is a significant increase from the $1.8 billion during the same period last year. The OIG reported 428 criminal actions against individuals or entities and 383 civil actions. In addition, 1,662 individuals and entities were excluded from participation in federal health care programs. To increase its fraud and abuse enforcement powers, on March 1, 2016 CMS issued a proposed rule which, if adopted, would allow CMS to deny or revoke Medicare enrollment to health care providers affiliated with entities or individuals that pose an undue risk of fraud, waste, or abuse. Under the proposed rule, providers would be required to disclose any affiliations with entities or individuals who currently have: (a) Medicare, Medicaid, or Children's Health Insurance Program (CHIP) debts; (b) are the subject of a payment suspension or exclusion from federal health care programs; or (c) have had their enrollment in Medicare, Medicaid, or CHIP revoked or denied. In keeping with its enforcement efforts, in June a Medicare Fraud Strike Force action in 36 different cities resulted in criminal and civil charges against 301 individuals for their alleged participation in health care fraud schemes causing approximately $900 million in false billings.

8. **CMS Issues Final 60-Day Medicare Repayment Rule**. This year, the Department of Health and Human Services (HHS) published a Final Rule concerning the return of Medicare overpayments. Pursuant to the Final Rule, Medicare providers are required to report and return overpayments to Medicare within 60 days after an overpayment is "identified" or face penalties. When the rule was initially implemented, there was debate about the definition of the term "identified". By some accounts, quantification of the overpayment amount was the critical factor that started the 60-day clock. In another view, the date the overpayment was initially identified was enough to start the clock, even though the exact amount of the overpayment was unknown. According to the Final Rule, the 60-day reporting period begins when either the provider has identified the scope of the overpayment or the day the provider received credible information of the potential overpayment if the provider failed to conduct a reasonable investigation. Therefore, notification of a possible overpayment does not start the 60-day clock, but rather requires a provider to exercise reasonable diligence to investigate. CMS requires that any investigation be completed within six months from receipt of credible information of an overpayment, absent extraordinary circumstances.

7. **Data Breaches and HIPAA Enforcement**. In 2016, health care data breaches and HIPAA penalties continued at an alarming pace. According to a Ponemon Institute report, data breaches have cost the health care industry $6.2 billion, with 79 percent of health care organizations reporting two or more data breaches in the past two years, and 45 percent reporting more than five breaches. The Office of Civil Rights (OCR) has taken notice and in 2016 we saw the largest fines ever imposed against health care providers for alleged HIPAA violations: Advocate Health Care $5.55M; Feinstein Institute for Medical Research, $3.9M; University of Mississippi Medical Center $2.75M; Oregon Health & Science University $2.7M; and New York Presbyterian Hospital $2.2M. The OCR has also increased enforcement actions against HIPAA Business Associates. In June of 2016, Catholic Health Care Services of the Archdiocese of Philadelphia, a business associate, paid $650,000 for violations of HIPAA stemming from the theft of an unencrypted mobile device containing health information on 412 individuals. In September, Care New England Health System, acting as a business associate, agreed to settle violations of HIPAA stemming from the loss of unencrypted backup tapes containing the ultrasound studies of approximately 14,000 individuals. Finally, HHS released guidance in July regarding ransomware and HIPAA and clarified: (1) that a ransomware attack is considered a "security incident" under HIPAA, and (2) that a ransomware attack will typically be considered a reportable HIPAA "breach" unless the affected provider can demonstrate a "low probability of compromise" of the data.

6. **Supreme Court Clarifies the False Claims Act Implied Certification Theory**. In general, the implied certification theory allows a False Claims Act (FCA) claim based on noncompliance with a statute, regulation or contractual provision without having to allege that the defendant explicitly misrepresented its compliance with that particular requirement when submitting a claim to the government for payment. In June, the Supreme Court issued a unanimous decision in the case of *Universal Health Services, Inc. v. United States ex rel. Escobar*, upholding a form of the "implied certification" theory. In Escobar, the Supreme Court identified two preconditions for an implied certification case. First, when a defendant submits a claim for government payment, the claim must not "merely request payment," it must also make "specific representations about the goods or services provided." Second, the defendant's failure to disclose noncompliance with material statutory, regulatory or contractual requirements must make those representations "misleading half-truths." In order to be actionable the misrepresentations must themselves be material to the Government's payment decision. The Court's opinion rejected the Government's position "that any

statutory regulatory or contractual violation is material so long as the defendant knows that the government would be entitled to refuse payment were it aware of the violation." By some accounts, this ruling will make it more difficult for the Government to bring FCA cases under the implied certification theory.

5. **CMS Overhauls Rules for Long Term Care Facilities**. In September, CMS issued a Final Rule imposing sweeping requirements for the approximately 15,000 long term care facilities in the United States. CMS said the new requirements, which were last updated in 1991, are aimed at, among other things, "reducing unnecessary hospital readmissions and infections, improving the quality of care, and strengthening safety measures for residents." One controversial change prohibits long term care facilities from using pre-dispute binding arbitration agreements, although the U.S. District Court for the Northern District of Mississippi recently issued an order temporarily blocking this new requirement. The Final Rule also addresses the training of nursing home staff, care and discharge planning, infection prevention and control programs, and long term care pharmacy services. CMS said the changes are expected to cost long term care facilities an estimated $831 million in the first year and $736 million per year thereafter, which breaks down to a first-year cost of approximately $62,900 per facility and a subsequent yearly cost of $55,000.

4. **Increase in ACA Premiums**. According to a report issued by HHS, the ACA has resulted in an estimated 20 million people gaining health insurance coverage since passage of the law. This additional coverage is provided through Medicaid expansion, Health Insurance Marketplace coverage, and changes in private insurance that allow young adults to stay on their parent's health insurance plans and requires plans to cover people with pre-existing conditions. However, a separate report from HHS finds that the average cost for the benchmark silver plan will increase next year by 22 percent. This increase, on average, will cost individuals $68 more a month (up to $362 a month), according to Modern Healthcare. Further, approximately 20 percent of people will only have one exchange insurance plan available as more insurers leave the exchanges citing financial losses. In Alabama, both UnitedHealth Care and Humana will not offer exchange plans in 2017, leaving BlueCross BlueShield of Alabama as the only option. These issues, however, may be moot under President-elect Trump. (See paragraph 1 below.)

3. **Alabama Medicaid RCOs in Trouble**. In order to try and control Medicaid costs in Alabama, legislation was passed in 2013 allowing for the establishment of regional care organizations (RCOs) in each of five designated regions in the State. In exchange for a capitated payment, each RCO would be responsible for providing health benefits to assigned Medicaid beneficiaries. The program was scheduled to begin October of this year, but was delayed until July 2017 after the Alabama legislature failed to allocate the necessary funds. In a special session, the legislature funded the program for two years by using BP oil spill money, a one-time funding source. Citing the lack of long-term funding, UAB, Viva Health and St. Vincent's have withdrawn from the RCO program, leaving only one RCO in two of the five regions. Rumors are circulating that other RCOs may also withdraw and the fate of the program appears to be in trouble.

2. **CMS Issues New Physician Payment Initiatives**. In October, CMS issued its Final Rule implementing the Quality Payment Program (QPP) portion of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The QPP implements a system of quality measures and reporting divided into two programs: the Merit-Based Incentive Payment Program (MIPS) and the Advanced Alternative Payment Models (APMs). MIPS applies to physicians, physician assistants,

nurse practitioners, nurse anesthetists, and clinical nurse specialists. These individuals will be evaluated based on four performance categories: quality, cost, clinical practice improvement, and meaningful use of electronic health records. CMS will begin collecting MIPS data beginning January 1, 2017 and will use that information beginning 2019. Participating providers can receive payment increases and decreases of up to four percent beginning 2019. Under APMs, providers who meet additional quality requirements and who receive 25 percent of Medicare payments or see 20 percent of their Medicare patients through an APM can qualify for additional incentive payments of up to five percent beginning 2019.

1. **Donald Trump Elected**. With the election of Donald Trump and with Republicans in control of Congress, we can expect legislation to repeal substantially all of the ACA. As part of the repeal, it is anticipated that funding for Medicaid expansion will be stopped and subsidies for exchange insurance plans will be phased out over a few years. Also, penalties for individuals who elect not to purchase insurance and employer penalties will be repealed. A full repeal without a replacement plan would mean that approximately 20 million fewer Americans would have health insurance, according to an estimate from the nonpartisan Congressional Budget Office. It appears less likely that Congress will repeal the ban on pre-existing conditions or the extended coverage option for young adults to stay on their parents insurance until age 26. President-elect Trump has also proposed modifying existing laws that inhibit the sale of health insurance across state lines, and allowing individuals to fully deduct health insurance premiums. The expanded use of health savings accounts is also one of his major proposals.

Howard E. Bogard
Partner

Birmingham Office
Phone (205) 458-5416
E-Mail hbogard@burr.com

Howard Bogard is Chair of the Health Care Practice Group at Burr & Forman LLP and exclusively represents health care providers in regulatory and corporate matters.