HALL RENDER
KILLIAN HEATH & LYMAN

HEALTH LAW NEWS

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HALL RENDER'S 2017 HEALTH LAW YEAR IN REVIEW

1) HEALTH INSURANCE MEGA-MERGERS CRASH TO EARTH AND OTHER ANTITRUST UPDATES

Dashed Mergers

In the area of antitrust law, 2017 saw the resolution of two health insurance mega-mergers. On January 23, 2017, the U.S. District Court for the District of Columbia ("U.S. District Court, D.C.") ruled in favor of the U.S. Department of Justice ("DOJ") in the government's suit to block the $37 billion insurance mega-merger between Aetna Inc. ("Aetna") and Humana Inc. ("Humana"). Then, on February 8, the same court blocked the proposed $54 billion merger between Anthem, Inc. ("Anthem") and Cigna Corp. ("Cigna"). In both cases, the parties subsequently abandoned the respective mergers.

In Aetna/Humana, the court largely analyzed the merger's projected impact on the market for Medicare Advantage, finding that the resulting entity would create "364 (very) highly concentrated markets, including 70 county-level monopolies" and was, therefore, presumptively anti-competitive. Mirroring recent decisions in provider merger cases, the court rejected the parties' argument that the efficiencies generated by the merger, specifically: (1) service line consolidations; (2) pharmacy cost reductions; (3) medical cost savings; and (4) clinical cost savings, would result in over $2 billion in annual cost savings and outweigh the anti-competitive impact of the transaction. Following the district court's decision, Aetna and Humana announced their intention to abandon the merger. Recently, it was reported that CVS Health Corporation agreed to buy Aetna for approximately $69 billion.

In Anthem/Cigna, the court shifted focus and analyzed the merger's projected impact on national accounts - that is, accounts with over 5,000 employees - and large group employers. The government also advanced a monopsony claim, arguing that the resulting entity would be able to dictate market terms, resulting in lower reimbursement rates, reduced access to medical care, reduced quality and fewer value-based provider collaborations. Following the U.S. District Court D.C.'s ruling, Cigna terminated the merger agreement and filed suit against Anthem, seeking a $1.85 billion break-up fee and $13 billion in damages. Anthem subsequently appealed the case to the U.S. District Court, D.C., which upheld the decision. Shortly after appealing that decision to the Supreme Court, Anthem too abandoned the merger. As of today, Anthem and Cigna are in an ongoing legal battle in Delaware State Court over the proposed break-up fee. This contentious litigation promises to stretch on for the foreseeable future.

Physician Practice Acquisitions in the Antitrust Spotlight

In addition to the health insurance mega-mergers, 2017 saw the Federal Trade Commission ("FTC") and state attorneys general challenge a number of physician practice acquisitions. On June 22, the FTC and the North Dakota Attorney General challenged the acquisition of a 61-physician multispecialty practice, by a North Dakota health system, alleging substantial harm to competition in four relevant service markets: (1) adult primary care physician ("PCP") services; (2) pediatric services; (3) OB/GYN services; and (4) general surgery physician services. The FTC's analysis indicated that the proposed transaction would result in market shares ranging from 77 percent to 100 percent of physicians offering the relevant services in the market, allowing the resulting entity to impose a small but significant non-transitory increase in price ("SSNIP"). Citing the FTC and DOJ's Horizontal Merger Guidelines, the FTC argued against the likelihood of new competitors entering the market in a manner that is "timely, likely, and sufficient in magnitude, character, and scope to deter or counteract the (anti) competitive effects." This argument by the FTC is aimed at a commonly used argument by providers that the anti-competitive effects of a transaction will be undermined by the entrance of new competitors. Here, the FTC cited the cold climate, the distance from major metropolitan areas and the substantial time and resources needed to recruit physicians to the area as "high entry barriers" that strengthened the FTC's case against the parties.

On August 31, the Washington state attorney general ("AG") filed a complaint to unwind a health system's ("Health System") affiliation with two physician practices. First, the AG challenged the Health System's acquisition of the assets of a 7-physician orthopedic practice in Silverdale, Washington, on traditional merger grounds analyzing product and geographic markets. Simultaneously, the AG alleged that the Health System's Professional Services Agreement with a 45-physician multispecialty group in Silverdale, amounted to little more than a price-fixing conspiracy among competitors. In addition to an injunction, the Washington AG is seeking disgorgement of profits and civil penalties.

Another case of interest took place in Minnesota. In early 2016, the FTC challenged a health system's ("Health System") acquisition of a medical group ("Medical Group") whereby the Health System would acquire all outstanding shares of the Medical Group and directly employ all of the Medical Group's physicians and advanced practice providers. The FTC alleged that the acquisition would substantially increase the Health System's market share to over 80 percent in three specific physician service markets: (1) adult primary care; (2) pediatric primary care; and (3) OB/GYN care. The parties defended the transaction by offering up a Failing Firm Defense, arguing that: (1) the Medical Group had no access to credit; (2) physicians had already left the Medical Group and would continue to do so absent the merger; and (3) the parties demonstrated that there were no alternative purchasers interested in acquiring the entire Medical Group. In consideration of these arguments, in January 2017, the FTC accepted a settlement whereby the Health System agreed to suspend physician non-competes, allow a certain number of physicians to leave and offer physicians a $100,000 departure bonus under certain circumstances.

Most physician practice acquisitions do not meet the Hart-Scott-Rodino reporting threshold so are not reportable pre-closing to the FTC. However, through complaints, industry press or other means, the FTC can become aware of these transactions and is willing to investigate and challenge lower dollar transactions that result in large market shares. As we've seen, like with hospital mergers, in physician acquisition cases, the FTC will employ its customary tools (HHI, Diversion, etc.) to determine product and geographic market competition.

On the Docket for 2018

2018 and beyond promise further merger activity and antitrust review. Consider these merger announcements:

- CVS to buy Aetna for roughly $69 billion;
- UnitedHealth Group to buy DaVita Medical Group for $4.9 billion;
- Advocate Health Care and Aurora Health Care agree to merge to create the nation's 10th largest not-for-profit health system;
- Dignity Health and Catholic Health Initiatives entered into definitive agreement to merge; and
- Ascension Health and Providence St. Joseph Health engaged in discussions to create the nation's largest hospital chain.

Hall Render will follow these proposed mergers as they develop. Please watch for future updates.

For more information on this topic, click here and here.

2) THE VIEW FROM CAPITOL HILL: SEARCH FOR A DEAL TO REPEAL THE AFFORDABLE CARE ACT

With the election of Donald Trump as President of the United States, Republicans on Capitol Hill made repeal of the Affordable Care Act ("ACA") their first legislative priority in 2017. The House of Representatives was first out of the gate with the introduction of legislation titled the American Health Care Act ("AHCA"), which passed the lower chamber by a vote of 217 to 213 on May 4. The effort then moved to the Senate where Republican lawmakers, limited by their use of a parliamentary procedure known as budget reconciliation, wrote their own bill instead of taking up the version passed by the House. The Better Care Reconciliation Act ("BCRA") was released in June but failed to garner enough support among moderate Republicans who were concerned by the bill's changes to Medicaid and failure to cover the same number of Americans as the ACA. Republicans were able to repeal the ACA's individual mandate via the tax reform legislation and have indicated they plan to revisit repeal in 2018. However, any such effort is not expected to be as comprehensive as what took place this year.

Even though the ACA repeal received most of the attention in 2017, other health care issues, such as the 340B drug discount program and Children's Health Insurance Program ("CHIP") funding, received attention as well. In November, CMS finalized a rule that drastically cut payment for 340B drugs from six percent on top of the average sales price to the average sales price minus 22.5 percent. This change, effective January 1, 2018, will result in an estimated $1.6 billion in cuts to 340B participating hospitals. (For further information, see *340B Drug Pricing Reimbursement Cuts Go into Effect January 1, 2018 - Case Dismissed* below.) Meanwhile, lawmakers allowed enhanced CHIP funding to expire on September 30 and failed to advance legislation to renew it before leaving town for the year. Leaders from both parties have indicated they intend to resolve their disagreement over how to pay for the funding and pass CHIP legislation early in 2018.

3) TAX REFORM ACT SIGNED INTO LAW IN THE WANING DAYS OF 2017: CHALLENGES AND OPPORTUNITIES FOR HOSPITALS AND OTHER TAX-EXEMPT HEALTH CARE ORGANIZATIONS

On December 22, 2017, President Trump signed the new Tax Reform Act (the "Act"). The Act contains numerous changes to the Internal Revenue Code that will affect tax-exempt hospitals and other health care organizations. Leaders of these organizations should begin 2018 by

giving careful attention to the new restrictions and planning opportunities to avoid adverse consequences later.

Repeal of Individual Mandate

Beginning in January 2019, the Act effectively repeals the so-called individual mandate that was originally enacted under the Affordable Care Act by reducing the applicable penalty tax to $0. Without the individual mandate, it is estimated that fewer people will obtain health insurance. For hospitals, fewer insured patients will likely mean increased bad debt as well as a greater reliance by patients on hospitals' financial assistance policies.

New Excise Tax on Executive Compensation

The Act imposes a new excise tax on tax-exempt organizations with highly compensated executive employees. More specifically, this tax applies to any "covered employee," which means someone who is one of the organization's five highest compensated employees or has been a covered employee in any year beginning with 2017. The tax applies generally to wages exceeding $1 million and to any "excess parachute payment," as calculated pursuant to this new provision. The tax does not apply to payments to physicians for medical services, so the concern for hospitals and health care organizations will be executive compensation. Since this new provision is not a prohibition, tax-exempt organizations will face a significant planning issue in evaluating whether to modify compensation packages or incur the tax.

Impact of Tax Reform on Tax-Exempt Financing for Hospitals

The Act did NOT repeal tax-exempt financing for private activity bonds, including 501(c)(3) bonds. The tax reform bill does prohibit new advance refunding bonds, but current refundings will still be available. However, the lowering of top corporate and individual income tax rates will likely affect the market for tax-exempt bonds. The spread in interest rates between tax-exempt and taxable financing is expected to narrow, and tax-exempt bank placements may become less common. For large issues from highly rated credits, taxable financings may be competitive with tax-exempt debt. To the extent the decrease in taxable rates leads to more health care activity taking place through taxable organizations, additional private business use of bond-financed facilities may arise.

UBIT-Activity Silos and NOLS

The Act modifies the unrelated business income tax ("UBIT") to require tax-exempt organizations to compute their tax liability separately for each trade or business activity (i.e., activity silos). This will prevent organizations from using net operating losses from one business activity to offset income from another. Meanwhile, the Act made several changes to the rules regarding net operating loss ("NOL") deductions. Changes include limiting NOLs to 80 percent of the taxpayer's taxable income, eliminating the ability for most taxpayers to carry back NOLs to prior years and extending the ability to carry forward NOLs to future years until the NOL is exhausted (pre-Act law limited carryforwards to 20 years). On a positive note, income from each separate activity will be subject to the newly lowered corporate tax rate. Overall, tax-exempt organizations with unrelated business activities, as well as existing or anticipated NOLs, will want to evaluate whether an alternative structure, such as a for-profit subsidiary, would be beneficial in order to better manage NOLs in relation to unrelated business activities.

Jeopardy to Charitable Contributions

The Act retained the charitable contribution deduction – and in fact increased the percentage of an individual's income that he or she may contribute to a charity in a tax year. Unfortunately for hospital foundations and tax-exempt organizations that rely upon donations for their financial survival, however, the law reduces the overall tax incentives for charitable giving. A primary issue is the doubling of the standard deduction, which will lead to fewer taxpayers itemizing their deductions and deriving a tax benefit for their gifts to charity. The reduced corporate tax rate and more limited estate tax amplify concerns about the amount of charitable giving. Estimates of the cumulative effect of these provisions vary, but charities certainly will want to enter into 2018 with a strong strategy for communicating the non-tax benefits for donors.

Employee Benefits

With respect to employee benefit-related provisions, the Act is more noteworthy for what it does not include rather than what it includes. For example, previously contemplated changes were not included for rules regarding nonqualified deferred compensation, dependent care expense reimbursement, adoption assistance, unrelated business taxable income for governmental plans, hardship distributions and the minimum age for in-service distributions. Nonetheless, the Act does include several notable changes, including elimination of the opportunity to recharacterize non-Roth IRA assets to Roth IRA assets, repeal of the tax exclusion for employer-provided qualified moving expense reimbursements (until 2026), except for military, the addition of a tax credit for employers who provide paid FMLA in excess of 50 percent of an employee's normal wages (2018 and 2019 only) and changes to the inflation adjustment provisions in many areas of the Internal Revenue Code so that the Chained Consumer Price Index for All Urban Consumers is utilized (resulting in smaller inflation adjustments in

future years).

Certain Expenses Subject to UBIT

The Act makes several changes that will effectively cause certain employee fringe benefit expenses to be characterized as unrelated business taxable income, which will create an additional tax burden for most tax-exempt organizations. Such benefits include qualified transportation fringe benefits, certain parking benefits and on-premises athletic facilities.

Practical Takeaway

Hospital leadership will need to move quickly to understand the new tax landscape. In the coming weeks, Hall Render attorneys will provide additional guidance concerning these high-impact areas, as well as other facets of the Act.

4) MICRO-HOSPITALS ON THE RISE: CMS ISSUED NEW GUIDANCE TO DEFINE "HOSPITAL"

Partly in response to the proliferation of micro-hospitals, on September 6, 2017, CMS issued Survey and Certification Memo 17-44 ("S&C Memo 17-44") with new guidance to state survey agencies ("SSAs") and accreditation organizations ("AOs") clarifying the definition of "hospital" as well as the survey procedures CMS expects SSAs and AOs to follow for purposes of determining whether a hospital meets the requirements for participation in the Medicare program. Hospitals failing to meet the statutory definition of "hospital" can be subject to either denial of certification by CMS for initial applicants or termination of the Medicare provider agreement for currently participating hospitals.

Micro-hospitals are licensed acute care facilities with a very small number of inpatient beds (as few as two) treating low-acuity patients. In order to participate in the Medicare program, hospitals must meet the statutory definition of "hospital" as set forth in Section 1861(f) of the Social Security Act (be "primarily engaged" in providing, by or under the supervision of physicians, to inpatients: (1) diagnostic services and therapeutic services for medical diagnosis, treatment and care of injured, disabled or sick persons; or (2) rehabilitation services for the rehabilitation of injured, disabled or sick persons) and also meet the applicable conditions of participation (e.g., the hospital must maintain clinical records on all patients, have 24-hour nursing services, have medical staff bylaws). For hospitals to participate in Medicare, it is not enough to meet state licensure requirements.

There is no single factor that determines whether a facility may be designated a hospital. Surveyors and the CMS Regional Office ("RO") must look at multiple factors to decide whether a facility may be certified as a hospital for Medicare participation purposes. S&C Memo 17-44 provides that a facility's average daily census ("ADC") (CMS expects the ADC of a hospital to be two or more inpatients) and average length of stay ("ALOS") (a stay is expected to cross two or more midnights) for all of its inpatient locations combined are important criteria in the determination of hospital status.

If a hospital does not have a minimum of two inpatients at the time of survey, a survey will not be conducted, although a surveyor will remain on site to conduct an initial review of the hospital's admission data, and a second survey may be attempted at a later date if the threshold ADC and ALOS criteria are met. If a facility is not found to have an ADC and ALOS of two or greater, then the hospital is not likely to be primarily engaged in inpatient care though the RO will consider other data gathered by the surveyor to make a determination on initial certification or decertification (e.g., the number of off-campus provider-based emergency departments, the volume of outpatient versus inpatient surgical procedures, patterns and trends in the ADC and staffing of the facility - if the ADC consistently drops to zero on the weekend, this may indicate the facility is primarily outpatient thereby not meeting the definition of hospital).

Health systems wishing to develop micro-hospitals as part of a continuum of care - especially micro-hospitals with a very small number of beds - should carefully consider the 2017 CMS guidance before dedicating resources to this endeavor. For more information on this topic, please click here.

5) LONG-TERM CARE FACILITIES: OVERHAUL OF 42 CFR PART 483 POSTPONED IN PART

In 2017, CMS suspended or postponed implementation of several aspects of the 2017 phase of the complete overhaul of Part 483 to Title 42 of the Code of Federal Regulations, the Requirements for States and Long-Term Care Facilities ("Final Regulations"). CMS's Final Regulations cover many regulatory requirements for long-term care facilities and create new compliance obligations for providers. They also seek to target re-hospitalizations, facility-acquired infections, overall quality and resident safety. The second phase ("Phase 2") of the Final Regulations became effective November 28, 2017.

CMS Suspends Enforcement of Penalties for Phase 2 Requirements and Revises F-Tags

On June 30, 2017, CMS provided a one-year restriction of enforcement remedies for specific Phase 2 requirements. The Survey and Certification Group at CMS issued a memorandum, "Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issues," addressing enforcement of Phase 2 requirements and wrote that it "will not utilize civil money penalties, denial of payment, and/or termination." If a facility is found to be out of compliance with the new requirements, CMS would use this year-long period to educate facilities about certain new Phase 2 quality standards by requiring a directed plan of correction or additional directed in-service training. CMS emphasized that this one-year period is not a change in the required implementation date for Phase 2 provisions.

The same memo announced that CMS had revised and re-numbered the F-Tags used to identify each regulatory part. CMS created a list of the F-Tags under each regulatory group and an F-Tag crosswalk that compares the prior F-Tags to the new F-Tags. The re-structuring of the regulation caused some tags to be combined while others were split into multiple subparts.

CMS Issues 18-Month Delay on Enforcement of Some Phase 2 Requirements for Long-Term Care Facilities

On November 24, 2017, the Survey and Certification Group at CMS issued a memorandum, "Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to Nursing Home Compare," to delay enforcement of additional provisions in the regulations. CMS issued the memo to address concerns about the implementation of the new requirements and new long-term care survey process and to make specific policy and process adjustments to the enforcement system and results posted on Nursing Home Compare website ("Nursing Home Compare"). The memo issued an 18-month moratorium on the imposition of civil money penalties (also known as CMPs), discretionary denials of payment for new admissions and discretionary termination where the remedy is based on a deficiency finding of one of eight specific Phase 2 F-tags.

CMS will use this 18-month moratorium period to educate surveyors and providers to ensure they understand the health and safety expectations that will be evaluated through the survey process as these Phase 2 requirements are associated with separate tags where specialized and technical assistance may be needed. CMS is not extending the moratorium to reporting reasonable suspicion of a crime due to its concerns about significant resident abuse going unreported. The 18-month moratorium on the imposition of remedies does not change the implementation date for the Phase 2 provisions, and the memo states that state survey agencies should cite these tags as appropriate and continue to forward their findings as normal.

CMS Temporarily Freezes the Health Inspection Five-Star Ratings

After the implementation of the new long-term care survey process on November 28, 2017, CMS will be holding constant or "freezing" the health inspection star rating system on Nursing Home Compare for health inspection surveys and complaint investigations conducted on or after November 28, 2017. CMS expects this freeze to begin in early 2018 and last approximately one year. The star rating system freeze will give long-term care facilities an opportunity to acclimate to the new survey requirements and process.

Most facilities will be surveyed for compliance with Phase 2 requirements using the long-term care revised survey process within one year after the November 28, 2017 Phase 2 implementation date.

For more information, click here, here and here.

6) HOME HEALTH UPDATE - 2017

New Home Health Conditions of Participation Go Final and Are Delayed

On January 9, 2017, CMS released a pre-publication copy of the Final Revised Home Health Conditions of Participation ("Final CoPs"). This was the final step in an effort to revise the Home Health CoPs that dated back to the proposed changes first published in October 2014. The Final CoPs adopted many changes as proposed but also included a number of significant changes to the proposals, including the addition of new standards.

The Final CoPs represent a sweeping change to the home health regulatory environment. They refocus surveyors on quality and outcomes. They make quality assurance and performance improvement ("QAPI"), previously treated as a defacto condition, a CoP that is central to and overarches the rest of the CoPs.

CMS Extends the Compliance Deadline for the New Home Health CoPs

When the Final CoPs were formally published in January 2017, the compliance deadline was July 13, 2017. As 2017 unfolded, however, there was a noted absence of surveyor training or revision to the State Operations Manual and/or Interpretive Guidelines. Providers became very

concerned about the rapidly approaching deadline and the lack of any guidance or other information from CMS. On April 4, 2017, CMS proposed to delay the compliance deadline by six months. On July 10, 2017, CMS published a final rule formally delaying the compliance deadline to January 13, 2018. Providers were grateful for the additional time but disappointed that no additional guidance was provided.

CMS Publishes Draft Interpretive Guidelines for the New Home Health CoPs

On October 27, 2017, CMS issued draft Interpretive Guidelines for the new Home Health CoPs ("IGs"). The IGs provided some additional guidance, but they left many questions unanswered and, in some cases, generated further questions. In comparison to the last survey and certification letter CMS issued addressing home health surveys, the IGs were surprisingly brief at only 85 pages. The IGs did not explain how the new conditions broke down into the current survey process. They provided fewer examples of probes surveyors should ask. In some cases, they simply reformulated the standards they were interpreting. The IGs' focus on QAPI, infection control and patient rights, provides a strong indication that providers should expect surveyors to focus on these areas in January. Overall, the industry was disappointed at the lack of clear guidance provided. As of January 10, 2018, no final guidelines had been published.

Although the IGs have not been finalized, CMS did provide surveyor training in early December.

CMS Announces that Home Health Survey Sanction Civil Money Penalties Will Be Suspended until January 13, 2019

On November 15, 2017, as provider concerns about the new final CoPs continued to mount, CMS informed the industry that it was advising the regional offices that, for one year after the final implementation date, they should not impose CMPs on home health agencies for condition-level deficiencies under the new CoPs. This delay will run from January 13, 2018 - January 13, 2019. CMS indicated that other alternative sanctions will be available, and CMPs will be available when a home health agency is identified to be in an immediate jeopardy situation. In all cases, condition-level non-compliance will result in the home health agency being placed on the termination track, and termination will continue to be the outcome for agencies that fail to achieve compliance.

CMS Announces, and Later Withdraws, a New Home Health Payment Model

As part of the CY 2018 Home Health Prospective Payment System Proposed Rule, CMS announced its plan to implement a sweeping reform of home health payment, the Home Health Groupings Model ("HHGM"). HHGM would have made a number of changes to home health reimbursement, including a move to 30-day episodes using a very different scoring model. As proposed, HHGM created a great deal of concern for the home health industry. Estimates of the financial impact on the home health industry ranged from CMS's projection of a $950 million reduction in home health reimbursement to industry projections of a roughly $4 billion reduction.

Ultimately, CMS withdrew the proposal after it received 1,300 comments opposing HHGM. However, the industry cannot be complacent. CMS likely still intends to modernize the home health payment system, and HHGM may simply be tweaked going forward. When CMS introduces future payment reform proposals, home health agencies should carefully review any proposed rules, technical papers and provider education materials and provide feedback to CMS.

7) 340B DRUG PRICING REIMBURSEMENT CUTS GO INTO EFFECT JANUARY 1, 2018 - CASE DISMISSED

In a buzzer-beater end of year decision issued on December 29, 2017, the U.S. District Court, D.C. denied a motion to enjoin looming major Medicare payment cuts to certain categories of hospitals that participate in the 340B Drug Pricing Program ("340B Program") scheduled to take effect on January 1, 2018. The 340B Program payment cut was incorporated in the 2018 Hospital Outpatient Prospective Payment System Final Rule finalized on November 1, 2017. Therefore, effective January 1, 2018, Medicare payment for 340B Program drugs is based on the drugs' Average Sales Price ("ASP") less 22.5 percent, a significant reduction (almost 27 percent!) from the former ASP plus 6 percent.

The U.S. District Court, D.C.'s decision responded to a lawsuit filed on November 13, 2017 by the American Hospital Association, Association of American Medical Colleges, America's Essential Hospitals and other individual hospitals (the "Plaintiffs") against the U.S. Department of Health and Human Services ("HHS") in an attempt to postpone the payment cut. The Plaintiffs' principal argument was that HHS exceeded its statutory authority in implementing the 340B Program payment cut. The U.S. District Court, D.C. dismissed the case on procedural grounds insofar as the Plaintiffs had not yet presented any actual claims for reimbursement to HHS. Therefore, the Plaintiffs may be able to pursue their claims on substantive grounds now that the 340B Program payment cut is in effect.

Background

The 25-year-old 340B Program provided for markedly discounted outpatient drug pricing for separately payable prescription drugs and biologics, other than vaccines, for participating hospitals (DSH hospitals, CAHs, rural referral centers, sole community hospitals, children's

hospitals and freestanding cancer hospitals) and other health care entities providing services to uninsured and low income patients ("Covered Entities").

Until January 1, 2018, select outpatient drugs were generally reimbursed by Medicare to Covered Entities at ASP plus six percent. According to HRSA, the 340B Program was designed to enable Covered Entities to stretch their federal reimbursement dollars to pay for services Covered Entities provide to the poor. The 340B statute does not, however, restrict how revenue generated by reimbursement (exceeding the discounted prices) may be used. Some critics believed that Covered Entities may have been using 340B-related revenues for profit rather than to augment health care services in the local community. As justification for the significant payment cut, CMS expressed concerns that previous payments under the 340B Program were "well in excess" of overhead and acquisition costs, resulted in overutilization of hospital-based services and were not linked to an increase in charity care. Accordingly, CMS reduced reimbursement for select outpatient drugs for DSH hospitals, rural referral centers and urban sole community hospitals. Notably, the payment cuts do not apply to CAHs, rural sole community hospitals, children's hospitals, PPS-exempt freestanding cancer hospitals or non-excepted off-campus provider-based departments established after November 2, 2015 that are paid under the Medicare Physician Fee Schedule.

Implications/What's Next?

Now that the payment cut is in effect, 340B Covered Entities must ensure that appropriate billing modifiers are implemented in drug payment claims submissions. The modifiers indicate whether the drugs being billed were purchased under the 340B Program.

340B Program Covered Entities should contact their federal representatives to communicate the true impact of the payment cuts.

Hall Render is evaluating options for establishing a Medicare group appeal challenging the validity of the 340B payment cuts. Stay tuned for further information.

For more information, click here and here.

8) CMS UPDATED SRDP PROTOCOL: NEW MANDATORY FORM

On March 18, 2017, CMS published on its website an updated Physician Self-Referral Disclosure Protocol ("SRDP") along with a copy of a new mandatory SRDP form to be used for all disclosures made on or after June 1, 2017. CMS characterized the new SRDP form as a means to "streamline and standardize" the disclosure process as well as to decrease the burden on disclosing parties. However, some stakeholders describe the updated SRDP form as requiring a more detailed and extensive self-disclosure response. Here's why:

> *Pervasiveness of Non-Compliance.* The new SRDP Form requires providers to identify the "pervasiveness of noncompliance" as part of any disclosure. This means the provider must describe how common or frequent the disclosed noncompliance was in comparison with similar financial relationships between the disclosing party and its referring physicians. The description of the pervasiveness of noncompliance must be quantitative and must provide examples. This requirement can be burdensome (especially when there are many physicians implicated in the noncompliance) insofar as the disclosing party must review all similar financial relationships for a six-year lookback period.
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> *Separate Physician Information Form for Each Physician*. Under the updated SRDP, the disclosing party must submit a separate Physician Information Form, or PIF, for *each* physician party to a non-compliant arrangement. Each PIF must include a narrative description of the arrangement, the remuneration/compensation provided under the problematic arrangement and the date of discovery of the non-compliant arrangement. With the addition of the mandatory PIF, it is no longer sufficient to merely reference a physician group, party to the arrangement.
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> *Financial Analysis Worksheet*. The disclosing party also must submit in Excel-compatible format a financial analysis of the potential overpayment for each physician included in the SRDP. The worksheet must include the physician's name and NPI, the date the overpayment was identified and the overpayment attributable to the physician's prohibited referrals itemized by calendar year. While the worksheet purportedly expedites CMS's review and confirmation of the submitted data, the new formatting requirement is more detailed than was expected in the past.
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> *Notes from the Field*. In our experience, the SRDP form does not really "streamline" the disclosure process since many self-disclosing parties opt to include a cover letter with the form in the disclosure packet. On the other hand, it is efficient to have the "pervasiveness of noncompliance" information included in the form since prior to rolling out the mandatory form, CMS would request this information

in a follow-up to a pending initial self-disclosure.

It remains to be seen whether the new form, overall, will lead to fewer supplemental information requests from CMS or otherwise will reduce the backlog and time period for resolution of Stark self-disclosures.

For more information on the updated SRDP, please click here. Our attorneys are familiar with the new form and can assist with the disclosure process.