Health Care Practice Group

Cinde Warmington
Chair
cwarmington@
shaheengordon.com

William E. Christie
wchristie@
shaheengordon.com

Steven M. Gordon
sgordon@
shaheengordon.com

Lucy J. Karl
lkarl@
shaheengordon.com

Donald Crandlemire
dcrandlemire@
shaheengordon.com

Benjamin Siracusa Hillman
bsiracusahillman@
shaheengordon.com

www.shaheengordon.com

Tenacity, Creativity and Results are the three words that best describe Shaheen & Gordon's approach to addressing complex legal issues. Our health care team closely monitors the rapidly changing legal environment so that our clients are prepared to meet the challenges of today as well as tomorrow. Relying on a wealth of experience, we offer practical advice and assist in implementing recommendations tailored specifically to meet the needs of both large and small health care clients.

FEDERAL DEVELOPMENTS

Affordable Care Act Implementation

SUPREME COURT UPHOLDS SUBSIDIES IN STATES USING FEDERAL MARKETPLACE

On June 25, the Supreme Court of the United States held that premium subsidies provided to eligible consumers who purchase insurance on the federally-operated health insurance marketplaces are consistent with the Affordable Care Act's statutory language and scheme. Challengers had argued that the Affordable Care Act prohibited the federal government from providing premium subsidies except where states operated their own marketplaces. The Supreme Court rejected this argument, holding that Congress' intent was that premium subsidies be available nationwide.

The ruling will allow individuals who purchase their health insurance coverage in states that utilize the federal marketplace, including New Hampshire, to continue to receive premium subsidies based upon their income. Had the Court sided with the challengers and held that the provision of such subsidies violated the Affordable Care Act, a substantial number of individuals would have been forced to drop their insurance coverage.

ADMINISTRATION FINALIZES RULE REGARDING SUMMARIES OF BENEFITS AND COVERAGE AND UNIFORM GLOSSARY

On June 16, the Treasury Department, Internal Revenue Service, Employee Benefits Security Administration, and CMS issued a new final rule regarding summaries of benefits and coverage (SBC) for plans and insurers. The rule took effect on August 17. This rule amends final regulations published in 2012.

The purpose of the rule is to assist plans and individuals to better understand their health coverage, and the rule amends the disclosure requirements to that end. Under the new rule, group health plans and group health insurers must make a separate SBC available for each benefit package offered. The SBC must be distributed at the time application materials are distributed to the potential enrollee, but if application materials are not distributed, then no later than the first date on which a participant or beneficiary is eligible to enroll. The full insurance policy or group certificate of coverage must also be made available online to all actual and potential enrollees.

The proposed rule also included revisions to the SBC template, instruction guides, and the uniform glossary provided to help consumers understand insurance terms. The Administration did not finalize this part of the rule, but anticipates doing so in early 2016, for SBCs issued in connection with coverage that begins on or after January 1, 2017.

NUMBER OF UNINSURED AMERICANS CONTINUES TO DECLINE

According to the National Center for Health Statistics, from early 2013 to early 2015, the number of Americans without health insurance dropped by 15.8 million, or one-third of the 2013 total. 29 million people, or 9.2 percent of Americans, were uninsured in early 2015, as compared with 14.4 percent of Americans in early 2013.

Although not included in the above statistics, last month, the U.S. Department of Health and Human Services announced that through June 30, close to a million additional individuals had enrolled in health insurance coverage through the federal health insurance marketplace following the close of open enrollment on February 22. Such individuals had the option to enroll outside the open enrollment period as the result of experiencing a qualifying life event, such as having a baby, or otherwise qualified for a special enrollment period under federal rules.

AVERAGE BENEFIT COSTS FOR NEWLY ELIGIBLE ADULT MEDICAID ENROLLEES ARE SUBSTANTIALLY HIGHER THAN THOSE OF NON-NEWLY ELIGIBLE ADULTS FOR 2014

In July, CMS's Office of the Actuary released its annual report on Medicaid's financial outlook. Significantly, the average benefits costs in 2014 for newly eligible adults (under the Affordable Care Act's Medicaid expansion) are estimated to be $5,517, or 19 percent greater than the average benefit cost for non-newly eligible adults of $4,650. In prior reports, the Office had projected that average costs for the newly eligible adult population would be 1 percent lower than those for non-newly eligibles. Newly eligible adults are estimated to have accounted for 4.3 million out of the 5.7 million increase in Medicaid enrollees from 2013 to 2014.

Reasons for the disparity between the earlier predictions and the current estimate include that when Medicaid expansion was done through managed care contracts, average capitation rates were significantly higher than earlier projections. In particular, the rates included adjustments to reflect a higher level of acuity or morbidity among newly eligible adults, projections of increased utilization based upon pent up demand, and adjustments based upon the notion that those with the greatest health care needs would be the quickest to enroll. The contracts themselves took into account uncertainty through the use of "risk-sharing arrangements" between states and managed care companies. The report predicts that once all the numbers for 2014 have been tallied later this year, some funds, and potentially significant funds, would be returned to the states and federal government by the managed care companies.

The report predicts that per enrollee costs for newly eligible adults will drop significantly starting in 2016. Across the entire Medicaid program, the Actuary now projects that spending for 2013 through 2022 will be 5.3 percent lower than predicted in last year's report, as a result of slower per enrollee expenditure growth than expected, lower projected increases in utilization, and lower projected overall Medicaid enrollment.

SOME MARKETPLACE PARTICIPANTS ARE MISSING OUT ON COST SHARING REDUCTIONS

Under the Affordable Care Act, enrollees in marketplace plans with incomes between 100% and 250% of the Federal Poverty Level are eligible not only for premium tax credits but also cost sharing reductions. That is, for a given plan, eligible individuals are able to obtain lower deductibles, copayments, and coinsurance as compared with individuals not eligible for such reductions. However, eligible individuals are only entitled to obtain cost sharing reductions when they enroll in a Silver Plan. Premiums for Bronze plans are typically cheaper than those for Silver plans, but with the cost-sharing amounts unreduced on Bronze plans, the overall cost of care for someone eligible for a cost-sharing reduction who nevertheless

chooses a Bronze plan can end up being substantially higher.

A private company, Avalere Health, conducted a study and found that while 8.1 million individuals with incomes that made them eligible for cost-sharing reductions had enrolled in marketplace plans, only 5.9 million are actually receiving them. The Congressional Budget Office, too, has projected that 3 million individuals who are eligible for cost-sharing reductions will nevertheless enroll in Bronze Plans and forego them.

NATIONAL TAXPAYER ADVOCATE REPORTS THAT APPROXIMATELY 300,000 TAXPAYERS PAID THE PENALTY FOR NOT HAVING HEALTH INSURANCE, DESPITE BEING ELIGIBLE FOR AN EXEMPTION

In July, the National Taxpayer Advocate reported that approximately 10.7 million taxpayers filed 2014 federal income tax returns claiming exemptions from the health insurance coverage requirements of the Affordable Care Act, while 6.6 million taxpayers filed returns that included payment of an "Individual Shared Responsibility Payment," the penalty that those who elect not to enroll in coverage must pay. The report found, however, that 300,000 of these individuals overpaid the penalty or paid it despite qualifying for an exemption, with an average overpayment of $110 per tax return. (There are a number of exemptions from the penalty; most of the individuals who overpaid the penalty qualified for an exemption for having low incomes.) The National Taxpayer Advocate has called for the IRS to issue refunds to such individuals without requiring any action on their part, particularly in circumstances where the IRS already has the information to make the adjustment on its own.

CMS PROVIDES SPECIAL ENROLLMENT PERIOD FOR MARKETPLACE ENROLLEES WHOSE DEPENDENTS' SOCIAL SECURITY INCOME WAS INCORRECTLY INCLUDED IN THEIR DETERMINATION OF HOUSEHOLD INCOME

An individual enrolling for health insurance on the federal marketplace has his or her eligibility for premium tax credits and cost-sharing reductions determined by looking at household income. Income from a tax dependent (regardless of the dependent's age) is included in household income only if the tax dependent is required to file a federal income tax return. When a dependent has income only from Social Security benefits, he or she does not have an obligation to file an income tax return, and so his or her income is not counted as part of household income for purposes of determining eligibility.

Prior to April 17, 2015, the federal marketplace erroneously included the income of certain tax dependents with only Social Security income in the household income calculation. Individuals affected by this problem were entitled to premium tax credits and cost sharing reductions that they did not in fact receive. CMS is now notifying affected individuals, who have 60 days from the date of the notice to update their application and make changes retroactively back to their original coverage date for 2015. They can apply any newly received advance premium tax credits or cost-sharing reductions to their current or a different plan prospectively, to their current or a different plan retroactively, or enroll in an new plan using the updated amount.

Other Federal Developments

CMS ISSUES MEDICARE PHYSICIAN FEE SCHEDULE PROPOSED RULE FOR FY 2016

On July 8, CMS released the 2016 Medicare Physician Fee Schedule Proposed Rule. There are a number of changes of considerable note. Some are related to further implementation of the ACA and some address the continuing shift from fee-based payment for services to quality and performance-based

payment.

The Proposed Rule includes changes arising out of the **Medicare Access and CHIP Reauthorization Act (MACRA)**. The Act, signed into law in April of this year, introduces significant physician payment reforms including Alternative Payment Models (APM) and the Merit-Based Incentive Payment System (MIPS) that will replace current incentive systems, such as Meaningful Use and PQRS, effective in 2019. Under the MIPS program, DHHS is charged with developing methodologies for assessing provider performance and, to that end, CMS is currently is seeking comment on a number of factors including determining the appropriate low-volume threshold for eligibility in MIPS and evaluating the key criteria in measuring clinical practice improvement.

CMS stated its intent to modify **Medicare's "Incident To" rules** in ways that may significantly impact physician practices. The Proposed Rule a) would require that the physician who bills for the "incident to" service also be the supervising physician and b) would prohibit the provision of "incident to" services by auxillary personnel who have been excluded from participation in Medicare, Medicaid and other federal health care programs or had their enrollment revoked for any reason. CMS also seeks comment on how to better ensure that "incident to" services are provided by qualified individuals by, among other things, creating new enrollment categories and requiring the use of modifiers to identify the types of individuals providing services.

The Proposed Rules expands **Chronic Care Management (CCM)** reimbursement to Federally-Qualified Health Centers and Rural Health Clinics for CCM services that are not already included in payments to FQHCs and RHCs. CMS also proposed separate payment codes for physicians conducting **Advanced Care Planning sessions.**

Modifications to the rules for billing and payment of **Medicare telehealth services** include the addition of codes covered by Medicare for prolonged services in the inpatient or observation setting and ESRD home dialysis services. Codes for other services such as evaluation/management services, pain management, palliative care and telerehabilitation codes were rejected from coverage. Under the Proposed Rule, CRNAs (Certified Registered Nurse Anesthetists) will also be eligible for reimbursement for listed telehealth services.

CMS has proposed changes to the **Medicare Shared Savings Program (MSSP)** regulations pertaining to quality measures, health information technology incentives, and beneficiary assignment to Accountable Care Organizations (ACOs). In order to be eligible for the MSSP, an ACO must perform at a certain level on specific quality measures. A new quality measure, station therapy for the prevention and treatment of cardiovascular disease, will be added to the list of quality measures for 2016.

The proposed rule would create several new exceptions and revise current exceptions under the **Stark Self-Referral Law** and would seek to reduce the burden of compliance. More specifically, the Proposed Rule provides some relief for what are often referred to as technical violations of Stark such as unsigned or expired agreements or arrangements documented in a series of writings. Technical and substantive amendments include the following:

Technical Changes:

- A single formal written document would not be required to satisfy the compensation exceptions such

as the personal services exception and the space and equipment rental exceptions. In some cases, a collection of documents, including contemporaneous documents showing the course of conduct, could satisfy the requirement.

- No explicit term would be required to satisfy the one-year term requirement in the personal services or space and equipment lease exceptions. A collection of documents or a showing that the agreement did in fact last one year could suffice.
- The current holdover period of six months may be extended if certain safeguards are met.
- The fair market value exception would be amended to permit renewal periods exceeding one year.
- Current regulations governing the timeframes for coming into compliance with the signature requirement would be amended to allow 90 days to obtain the signature whether or not the non-compliance was inadvertent.

Regulatory Changes:

- CMS has proposed a new exception to allow hospitals, FQHCs and Rural Health Centers to provide financial assistance to assist a physician to employ certain non-physician practitioners under specified circumstances.
- The Proposed Rule revises the definition of geographical service areas for FQHCs and RHC relying on the physician recruitment exception to Stark.
- The definition of remuneration would be revised to clarify that the provision of items, devices or supplies used solely to collect, transport, process or store specimens for the entity providing the items, devices or supplies or for the communication of results of tests or procedures does not constitute remuneration under Stark.
- The stand-in-the-shoes rules would be revised to clarify that all physicians in a physician organization would be considered parties to a compensation arrangement between the physician organization and a designated health services (DHS) entity.
- A new proposed exception would allow for timeshare arrangements between a hospital or physician organization and a physician for space, equipment, personnel, items, supplies and services, which are used predominantly to furnish evaluation and management services to patients of the physician.

CMS has also proposed changes to **the PQRS and the Physician Compare Website.** Additional PQRS measures will be added in 2016 and duplicative measures will be deleted. CMS is considering whether or not to report the Open Payments data on the Physician Compare Website, and is seeking comments.

Lastly, CMS has proposed that the **Medicare Opt-Out** regulations be amended to reflect changes adopted under MACRA providing that the opt-out affidavits submitted by physicians and other practitioners on or after June 16, 2015 will automatically renew every two years unless the automatic renewal is cancelled at least 30 days in advance.

CMS PROPOSES CHANGES TO OUTPATIENT PROSEPCTIVE PAYMENT SYSYTEM

On July 8, CMS published the 2016 Outpatient Prospective Payment System (OPPS) Proposed Rule. Highlights include:

- A proposed 2 percent reduction in the OPPS update to correct a 2014 estimate that resulted in increased payment. CMS estimates the reduction would result in a $43 million decrease in payment.

- Changes to the two-midnight rule: The proposed rule would allow payment under Medicare Part A on a case-by-case basis for stays where the physician expects the patient to need less than two midnights of hospital care. The factors to be considered include, among others, the severity of the patient signs and symptoms, the predictability of an adverse event, and the need for diagnostic studies.
- Chronic care management (CCM) services: CMS proposes additional requirements for payment of CCM services including, (i) the patient must have received hospital services within the last 12 months; (ii) documentation that all elements of CCM services were explained or offered; (iii) the beneficiaries' acceptance or denial of services; (iv) use of a certified electronic health record; (v) defined elements of CCM services are included; and (vi) only one hospital may be paid for such services during a calendar month.
- There are a number of other proposals including, but not limited to, packaging payment for some drugs into surgical procedures, changes to the laboratory test packaging policy, the creation of 9 new ambulatory payment classification codes and changes in certain hospital outpatient quality reporting measures.

CMS EXTENDS TWO-MIDNIGHT RULE ENFORCEMENT DELAY

- On August 12, CMS announced that it will extend the enforcement delay of the two-midnight rule until December 31, 2015. The current delay was set to expire on October 1. During this additional delay, short stay inpatient hospital reviews will be based on Medicare's current payment policies. Unless there is another delay, patient status reviews will be conducted in accordance with the rule and with changes adopted under the 2016 Outpatient Prospective Payment System Final Rule as discussed above.

CMS ISSUES 2016 INPATIENT PROSPECTIVE PAYMENT SYSTEM FINAL RULE

On July 31, CMS issued the 2016 Final Rule to update Medicare payment policies and rates under the Inpatient Prospective Payment System (IPPS). The Proposed Rule was issued on April 17th. The rule is effective on October 1. Major provisions include:

- Increased operating payments of 0.9 percent or $378 million, for acute care hospitals paid under IPPS that successfully participate in Hospital Inpatient Quality Reporting and demonstrate meaningful use of certified electronic health record technology. This is down from the 1.1 percent projected in the Proposed Rules that was released in April. Hospitals that do not submit data will lose one quarter of the market basket update (2.4 percent) and those that do not meet meaningful use requirements will lose one half of the market basket update. There will also be a 2.3 percent increase, or $187 million, in capital payments to IPPS hospitals for a total of $565 million.
- Hospitals in the lowest quartile with regard to hospital acquired conditions will suffer payment reductions of 1 percent.
- Medicare disproportionate share hospital payments will be reduced by $1.2 billion with CMS attributing the decrease primarily to continued declines in the number of uninsured individuals since the passage of the Affordable Care Act.
- Seven new measures will be added to the Hospital Inpatient Quality Reporting program.
- The Hospital Value-Based Purchasing Program is amended to add a care coordination measure beginning in FY 2018 and a 30-day mortality measure for chronic obstructive pulmonary disease for FY 2021.

DEPARTMENT OF HEALTH AND HUMAN SERVICES ISSUES PROPOSED OMNIBUS GUIDANCE ON 340B DRUG DISCOUNT PROGRAMS

On August 28, DHHS, through the Health Resources and Services Administration (HRSA), issued proposed guidance on the 340B program, which allows certain health care providers access to lower-priced drugs. The guidance covers the types of entities which are eligible to participate in the program and requests comments related to the eligibility of hospital outpatient facilities that are located off-site. The comprehensive proposed guidance also addresses, among other things, the registration, termination and recertification process, the definition of eligible individuals, the prohibition on duplicate discounts and the maintenance of records.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ISSUES PROPOSED NON-DISCRIMINATION RULE

On September 8, the U.S. Department of Health and Human Services Office for Civil Rights published a proposed rule implementing the Affordable Care Act's non-discrimination provision. Section 1557 of the Affordable Care Act extended civil rights protections banning sex discrimination to health programs and activities, and prior civil rights laws barred discrimination based on race, color, national origin, disability, or age. All of these prohibitions have been incorporated into the new rule. The rule makes clear that individuals can seek legal remedies for discrimination under Section 1557.

Significantly, the proposed rule establishes that the prohibition on sex discrimination includes discrimination based on gender identity. The rule requires that individuals be treated consistent with their gender identity, including in access to facilities, and prohibits insurers from having categorical exclusions on coverage of care related to gender transition.

The rule also requires equal treatment of women and men not only in health coverage they obtain but in the health services they seek from providers. It bolsters language assistance for people with limited English proficiency, providing guidance on requirements for provision of oral interpreters and written translations. For example, covered entities will have to post a notice of consumer rights about communication assistance, with a "tagline" in 15 languages. If complaints are brought, the frequency with which an entity encounters individuals who speak the language at issue will be a factor in OCR's approach to such cases.

For individuals with disabilities, the rule contains requirements for the provision of auxiliary aids and services, including alternative forms and sign language interpreters, and the accessibility of programs offered through electronic and information technology.

The proposed rule applies to health insurance marketplaces, any health programs administered by HHS, and any health program or activity, any part of which receives funding from HHS. For example, hospitals that accept Medicare or Medicaid patients, and doctors who treat such patients, are subject to the rule. The rule also extends nondiscrimination protections to individuals enrolled in any plan offered by an insurer participating in the health insurance marketplace.

Finally, the proposed rule requests comment on whether it should include an exemption for religious organizations and what the scope of any such exemption should be.

MEDICARE PROGRAM ISSUES ACO FINAL RULE

On June 4, CMS released a final rule updating the Medicare Shared Savings Program. The final rule creates a new risk model (called "Track 3") which will allow MSSP providers to receive higher rates of shared savings, prospectively assign beneficiaries, and apply for waivers from the three-day inpatient stay requirement for Medicare coverage of skilled nursing facility services. CMS anticipates that the final rule will help to increase participation in the MSSP while providing additional flexibility to providers in the program and allowing them to focus more on primary care services.

CMS PROPOSES NEW PAYMENT MODEL FOR JOINT REPLACEMENTS

On July 9, CMS proposed a new bundled payment model for hip and knee replacements in an effort to address wide variances in both the cost and the quality of care associated with these procedures. Under the Comprehensive Care for Joint Replacement model, the hospital performing the procedure would be accountable for both the cost and the quality of the care from the time of the surgery and for 90 days thereafter. CMS believes this model will create appropriate incentives for hospitals to insure proper coordination of care with physicians, home health agencies and nursing facilities. This payment model would be available in 75 geographic areas nationwide and hospitals in those areas would be required to participate. Comments on the proposed rule were due on September 8.

OSHA ISSUES INSPECTION GUIDANCE FOR INPATIENT HEALTHCARE SETTINGS

On June 25, the Occupational Safety and Health Administration (OSHA) issued guidance for the inspection of hospitals, nursing and residential care facilities to focus on hazards commonly occurring in health care facilities including musculoskeletal disorders related to patient or resident handling, workplace violence, bloodborne pathogens, tuberculosis and slips, trips an falls. The guidance applies to all Federal OSHA inspections and, because the hazards are applicable nationwide, State plans are also expected to following the guidance.

CMS RELEASES 2014 OPEN PAYMENT DATA

On June 30, CMS released the 2014 Open Payments data under Physician Payment Sunshine Act showing $6.49 billion in financial transactions between pharmaceutical and device manufacturers and physicians and teaching hospitals. While the earlier release of the 2013 data was plagued by reporting inaccuracies, CMS reports that it was able to validate 98.8 percent of the all records in the Open Payments systems and that any records that could not be verified were rejected. The Open Payments data may be viewed at https://www.cms.gov/openpayments/.

DHHS ISSUED PROPOSED CHANGES TO REGULATIONS PROTECTING HUMAN RESEARCH SUBJECTS

On September 2, the Department of Health and Human Services and 15 other agencies issued proposed revisions to the so-called "Common Rule" which regulates the protection of human research subjects. The proposal would streamline consent forms, require consent for secondary research to be performed on a left over specimen (e.g. blood), and add more categories of exempt research while providing more oversight for research posing greater risks. New data security standards are also included in the proposal.

OIG ISSUES FRAUD ALERT WARNING OF PHYSICIAN COMPENSATION ARRANGEMENTS THAT MAY RESULT IN LIABILITY

On June 9, the OIG issued a Fraud Alert arising out of its recent settlement with 12 individual physicians who entered into *questionable* medical directorships and office staff arrangements. The

compensation paid to these physicians under their directorship arrangements were alleged by the OIG to constitute anti-kickback statute violations. More specifically, the payments to physicians took into consideration the volume or value of referrals, did not accurately reflect fair market value of services and were for services not actually performed. Additionally, the OIG alleged that some of the physicians were participating in arrangements wherein an affiliated health care entity paid the salaries of physicians' front office staff and that such payments constituted improper remuneration. Because the physicians were found to be an integral part of the scheme, they were subject to liability under the Civil Monetary Penalties Law.

OIG ISSUES FIVE ADVISORY OPINIONS

On June 19, the Office of the Inspector General ("OIG") issued advisory opinion **15-08** relative to a request regarding the use of a preferred hospital network as part of Medicare Supplemental Health Insurance ("Medigap") policies. The insurer would indirectly contract with hospitals for discounts on policyholders' inpatient deductibles and then offer a $100 premium credit to policyholder who used a network hospital for an inpatient stay. Finding a low risk of fraud and abuse and potential savings to policyholders, the OIG concluded that while the proposed arrangement could potentially generate prohibited remuneration, the OIG would not impose sanctions.

On July 23, the OIG issued Advisory Opinion **15-09**, which stated that the OIG would not impose administrative sanctions on four Medigap insurers for contracting with a preferred hospital organization (PHO) for discounts on Medicare Part A deductible fees. This opinion is similar to OIG Advisory Opinions 15-03, 15-05, and 15-08, wherein the OIG found that the proposed arrangements had a low risk of fraud and abuse due to their low likelihood of increasing utilization of Medicare payments. Much like in Advisory Opinion 15-08, the OIG allowed for a $100 credit to the policyholders, citing a potential lowering in cost for all policyholders.

On July 28, the OIG issued Advisory Opinion **15-10**, concluding that the OIG would not impose administrative sanctions on a hospital system for a proposed leasing arrangement. The proposed arrangement involved a non-profit hospital system leasing its non-clinician employees to a related psychiatric hospital at the full cost of salary, benefits, and overhead for those employees. The result would be a charge of less than fair market value to a potential referral source. The OIG found that the proposed arrangement posed a low risk of fraud and abuse because of the cost efficiencies between two related entities, the lower labor and operational costs that would be achieved and the lack of any evidence that the arrangement would increase incentives for referrals over those already existing between the related parties.

On August 12, the OIG issued Advisory Opinion **15-11**, stating that the OIG would not impose administrative sanctions under the anti-kickback statute on an existing program that provides free supplies of a cancer drug to patients who have experienced a 5 day delay in the insurance approval process. The program, sponsored by manufacturers, provides up to two free thirty-day supplies of the drug dispensed by specialty pharmacies. In its decision, the OIG distinguished this arrangement from what it described as problematic "seeding" programs where manufacturers offer drugs for free or at a reduced cost in order to induce the patient to obtain subsequent prescriptions that would be billed to Medicare. Here, the OIG determined that offering the free drug only in the limited circumstances where insurance approvals extend beyond 5 days is unlikely to induce a prescriber to choose this drug over another, particularly where alternative treatment options are limited as with this drug.

On August 13, the OIG issued Advisory Opinion **15-12** pertaining to free introductory visits by home health providers. The arrangement contemplates the hospital discharge planner providing a patient with a list

of home health providers. Once the patient makes a selection, the home health provider schedules an introductory visit and shares information that will facilitate the provision of services after discharge such as contact information, an overview of the home health care experience and pictures of the home health staff. No diagnostic or therapeutic services are provided during the visit. The OIG determined that because the introductory visits do not provide any actual or expected economic benefit to patients, they do not constitute remuneration and do not implicate the anti-kickback stature or the civil monetary penalty law.

FEDERAL COURT TO ADDRESS THE QUESTION OF WHEN AN OVERPAYMENT IS IDENTIFIED

On August 3, a Federal District Court for the Southern District of New York ruled that there was sufficient evidence indicating that four New York Hospitals operated by Continuum Health Partners, Inc. failed to comply with a 60-day payment deadline for returning Medicaid overpayments. The court found that the allegations sufficiently demonstrate that the defendants triggered the 60-day repayment requirement on February 4, 2011 when an employee preliminarily identified 900 instances of potential Medicaid overpayments totaling over $1 million. Four days after alerting management to the overpayments, the employee's employment was terminated. Over the next year, the Comptroller continued to alert Continuum to erroneous claims. Some claims were repaid over the course of the next two years, many after Continuum received a Civil Investigative Demand. Under a provision of the ACA, a health care provider is required to report overpayments within 60 days of the date it is identified. A key issue in the case is the date of identification, a point which has been the subject of much discussion but for which there has been an absence of regulatory guidance. The court found that the 60 days began on February 4 despite the fact the employee's report was preliminary and later proved to contain many inaccuracies.

DEPARTMENT OF JUSTICE ANNOUNCES "FIRST OF ITS KIND" SETTLEMENT FOR FAILURE TO RETURN OVERPAYMENTS UNDER THE FALSE CLAIMS ACT

On August 3, the Department of Justice announced the first False Claims Act settlement of a case involving a health care provider's alleged failure to investigate, identify and refund overpayment to government programs. Pediatric Services of America Healthcare and its related entities agreed to pay $6.88 million and enter into a corporate integrity agreement to resolve allegations first raised in whistleblower suits brought by two former employees who will receive $1.1 million as their share of the settlement. This is the first False Claims Act settlement based on a healthcare provider's failure to investigate credit balances in its records in order to identify potential overpayments. Under the Affordable Care Act, health care providers must report and return overpayments within 60 days after such overpayments are identified.

PRIVATE PHYSICIAN GROUP AGREES TO $750,000 HIPAA SETTLEMENT

On September 2, the Office of Civil Rights announced a $750K settlement with Cancer Care Group, PC, a private radiation oncology physician practice located in Indiana for what is described as "widespread non-compliance" with the HIPAA Security Rule. The settlement arises out of a breach notification made by the group in 2012 reporting a stolen laptop containing unencrypted protected health information of 55,000 individuals. The practice was cited for failing to conduct an enterprise-wide risk analysis when the breach occurred and failing to have a comprehensive device and media control policy.

DEPARTMENT OF JUSTICE BRINGS SUIT AGAINST FOUR MICHIGAN HOSPITAL SYSTEMS FOR VIOLATIONS OF FEDERAL ANTITRUST LAW

On June 25, the United States Department of Justice (DOJ) announced that it had filed suit against four Michigan hospital systems, Hillsdale Community Health Center, Community Health Center of Branch County, ProMedica Health System and W.A. Foote (d/b/a Allegiance Health), alleging they entered in unlawful agreements to divide up territories for marketing purposes in violation federal of antitrust laws. On

the same day, the DOJ announced that it had reached a settlement with the first three hospital systems which settled the allegations by agreeing not to enter agreements which prohibit or limit marketing within the territories of other service providers or to communicate about their marketing efforts or strategies in the future. Litigation against W. A. Foote Memorial Hospital is proceeding.

ICD-10 IMPLEMENTATION DEADLINE IS OCTOBER 1

Just a reminder that Medicare will no longer accept ICD-9 codes after September 30. In an effort to ease the ICD-10 transition, CMS and the American Medical Association (AMA) has been offering training and education programs and national calls to address providers' questions. In answering frequently asked questions, CMS stated that for 12 months Medicare will not deny Part B claims with the wrong ICD-10 code if it is a "valid" code in the right "family." In addition, physicians will not be subject to penalties under the quality reporting programs for using an incorrect ICD-10 code during the transition period.

State Developments

GOVERNOR VETOES STATE BUDGET

On June 25, Governor Hassan vetoed the $11.35 billion budget passed by the State House and Senate, citing non-negotiable differences in her budget versus the Legislature's. Of particular note are the Legislature's exclusion of expanded Medicaid, the lack of a pay increase for state employees and reductions to business taxes. The legislature passed a continuing resolution which will hold spending at current levels pending the adoption of a new budget.

UPDATE ON MEDICAL MARIJUANA PROGRAM

On June 9, the New Hampshire Department of Health and Human Services (NH DHHS) announced the selection of applicants to operate alternative treatment centers (ATC) under the therapeutic cannabis program. Successful applicants are Prime Alternative Treatment Centers of NH, Inc. (Geographic Area 2), Temescal Wellness, Inc. (Geographic Areas 1&3) and Sanctuary ATC (Geographical Area 4). Public input sessions have been held around the state. NH DHHS has proposed changes to its current rules to include statutory changes adopted by the legislature including expanding the list of qualifying conditions, removing requirements for annual photographs, removing the requirement for criminal records checks by designated caregivers, removing registry identification numbers from registration cards. Also included are rules to establish of a pre-registration process for patients and caregivers, prohibit the production of cannabis concentrate by certain methods and establishing a process for accepting petitions to approve medical conditions not currently on the list. It is expected that the ATCs will begin dispensing in the Spring of 2016.

GOVERNOR HASSAN CALLS FOR TOUGHER STANDARDS FOR PRESCRIBING OPIOIDS

On September 2, Governor Hassan called upon members of the New Hampshire Board of Medicine to adopt "stronger, more explicit and more up-to-date rules to prevent opioid abuse." She asked the Board to appoint a member to work with her office and the New Hampshire Department of Justice to take a harder look at opioid prescribing practices. The Governor was critical that the Board's current guidelines are framed as mere recommendations and called for more specific requirements such as ensuring that patients in emergency rooms receive no more than a three-day supply and requiring patient pain contracts. Sarah Blodgett, Executive Director for the Board agreed that some changes could be made but added that the Board and the state's medical providers have to strike a balance for patients who legitimately need pain medication.

EXECUTIVE COUNCIL APPROVES CHANGES TO MEDICAID MANAGED CARE CONTRACTS

At its August meeting, the Executive Council voted to approve a $1.6 billion contract extension with NH Healthy Families and Well Sense Health Plan, the two Medicaid managed care organizations that administer the state's managed Medicaid progam. The contract extension sets new rates to be paid for services provided and includes a provision that returns the community mental health centers to fee-for-service payment rather than the capitated per-member per-month payments they received under the prior contract. The proposed contracts run until June 30, 2017.

NH DEPARTMENT OF HEALTH AND HUMAN SERVICES APPROVES PREFERRED DRUG LISTS FOR MEDICAID MANAGED CARE ORGANIZATIONS

Effective October 1, the two NH Medicaid Managed Care Organizations (MCOs) will begin using their own Preferred Drug Lists administered under their own policies and prior authorization requirements. For new prescriptions, providers should use the Preferred Drug List of the patient's MCO. For ongoing prescriptions, the MCOs will provide continuity of coverage for up to six months, or until a medical necessity review is performed or the prior authorization expires. If the patient is taking a medication that can be switched to a clinically appropriate medication on the Preferred Drug List, the MCO will provide notice of the change.

NH DEPARTMENT OF INSURANCE ISSUES OPINION ON DIFFERENTIAL PROVIDER REIMBURSEMENT RATES FOR PATIENTS IN MEDICAID EXPANSION PROGRAM

On June 1, Roger Sevigny, Insurance Commissioner issued a bulletin addressing the question of whether a carrier may vary a provider's reimbursement within a silver-level Qualified Health Plan based on whether the patient is enrolled in New Hampshire's Medicaid expansion, the Premium Assistance Program or the private market. Citing New Hampshire insurance law making it an unfair trade practice to discriminate against individuals of the same class with respect to premiums or benefits payable, the Commissioner determined that carrriers may not adjudicate individual consumers' cost-sharing in a manner that results in different levels of payment. This may have significant contracting implications for providers as the Medicaid expansion population moves into the NH Health Insurance Marketplace. There will not be differential rates for the expansion population as compared to the individuals enrolled through the private market.

LEGISLATIVE UPDATES

These are our final updates on the Bills from the 2015 Legislative Session:

- HB 326: This bill clarifies certain membership positions on the board of registration of medical technicians by adding registered or certified health care providers to the list of those who can serve on the board. **Voted Ought to Pass with Amendment** by the House. The amendment changes the membership of the board to allow the inclusion of a medical technician, provides for sharing of the board's data with the OIG and other administrative changes. The Senate **passed** the amended bill and it was **signed into law by the Governor** on June 5 with an effective date or January 1, 2016.

- HB 330: This bill establishes an oversight commission for medical cost transparency to monitor and further develop the NH HealthCost Internet website. Voted **Ought to Pass with Amendment** by the House. The amendment changes the composition of the commission. Voted **Ought to Pass with Amendment** by the Senate further changing the composition of the commission. The House concurred with the Senate amendment and the bill was **signed by the Governor** on July 13.

- HB 422-FN: This bill allows physician assistants to certify death certificates and to authorize involuntary commitment and voluntary admission to state institutions. Voted **Ought to Pass with Amendment** by House Health and Human Services Committee (17-0). The amendment deletes the authority to authorize involuntary commitment and voluntary admission to state institutions. The Senate **passed** the amended bill and amended the bill in enrollment to correct grammatical errors. The House approved the amendment. The bill was **signed into law by the Governor** with an effective date of January 1, 2016.

- HB 476-FN: This bill adds several medical conditions to the definition of "qualifying medical condition" for the purposes of the law governing the use of cannabis for therapeutic purposes including epilepsy, lupus, Parkinson's disease, and dementia associated with Alzheimer's disease. Voted **Ought to Pass with Amendment** by the House. The bill was then introduced in the Senate and referred to the Health and Human Services Committee where it was voted **Ought to Pass with Amendment** (to add colitis). The bill was further amended on the Senate floor (colitis deleted) and **passed as amended**. The House **concurred** with the Senate amendments and the bill was **signed into law by the Governor** on July 6 with an effective date of September 2, 2015.

- HB 484: This bill modifies definitions, adds requirements for members appointed to the board of nursing and adds exemptions from licensure for administration of medications by assistive personnel and for attendant care services. **Voted Ought to Pass with Amendment** by the Executive Departments and Administration Committee (16-0). The amendment proposes language to clarify the authority of LNAs to administer medication in home care, residential care and adult day care settings and adds an exemption from regulation. The Senate **voted ought to pass with amendment** to add hospice as an additional setting. The House **concurred** with the Senate amendment. The bill was **signed into law by the Governor** on July 13 with an effective date of September 11, 2015.

- HB 508: This bill establishes a procedure for the dissolution of the New Hampshire medical malpractice Joint Underwriting Association (NHMMJUA). Introduced to House Judiciary Committee. **Voted Ought to Pass with Amendment** by Committee on Commerce and Consumer Affairs (15-1). The Amendment makes several technical changes but also includes a provision providing that the bill shall not be construed to alter any vested contractual rights that any class of NHMMJUA policyholders may have with respect to excess surplus of the NHMMJUA. The bill was introduced in the Senate and referred to the Executive Departments and Administration Committee. The Committee voted **Ought to Pass with Amendment**, as did the full Senate, adding two floor amendments. The Senate Committee Amendment makes some structural changes to the dissolution process but carries forward the provision regarding vested contractual rights. One floor amendment requires creation of a dissolution reserve for satisfying hardship claims by current policyholders. The other adds a provision that requires insurers covering oral anti-cancer therapies to require the same copayment, deductible or coinsurance amount for patient administered medication as for injected or intravenously administered anti-cancer medication. The bill was **further amended in a committee of conference and signed into law by the Governor** on July 20.

- HB 564-FN: This bill declares that a managed care health benefit plan offering prescription drug benefits to Medicaid recipients shall not require prior authorization for certain drugs used to treat mental illness. Voted **Ought to Pass with Amendment** by the House Health and Human Services Committee (13-4). The amendment makes the bill applicable to Medicaid managed care organizations rather than all managed care organizations. The Senate voted **ought to pass with amendment**. The amendment requires a managed care organization offering prescription benefits to Medicaid recipients to suspend

prior authorization requirements for a community mental health program for drugs used to treat mental illness and also requires HHS to report to an oversight committee. The House **Concurred with the Senate amendment** and the bill was **signed by the Governor** and was fully effective ion July 6.

- SB 23: This bill allows certain advanced practice registered nurses to authorize involuntary commitment and voluntary admission to state institutions. Voted **Ought to Pass** by the Senate Health and Human Services Committee. The bill was introduced in the House and referred to the Health and Human Services Committee. It was voted **Ought to Pass with Amendment** by the Committee and then the full House. The amendment corrected a technical error in the bill. Senator Sanborn concurred with the amendment and the bill was **signed into law by the Governor on June 12 and was effective upon signing.**

- SB 84: This bill clarifies when it is appropriate to use telemedicine. Under this bill, a practitioner shall not prescribe controlled drugs, Schedule II-IV, by means of telemedicine. Voted **Ought to Pass** by the Senate. The House voted **Ought to Pass with Amendment**. The amendment allowed for the prescribing of controlled drugs, Schedule II-IV after an initial in-person examination by a practitioner licensed to prescribe and then an annual in-person exam thereafter. The Senate did not concur and requested a committee of conference. The House acceded to the request and appointed a Committee of Conference. The bill was further amended to limit the prescribing of Schedule II-IV medications to only under specific circumstances and **signed into law by the Governor on July 13** with an effective date of September 11, 2015 except for specific provisions which specify different effective dates.

- SB 108-FN: This bill makes changes to the law governing the reporting of health care associated infections including expanding the list of facilities with a reporting requirement to include end-stage renal dialysis centers, nursing and other residential care facilities and assisted living residences. It is requested by the Department of Health and Human Services. Voted **Ought to Pass with Amendment** by the Senate. The amendment changed the requirement for tracking and reporting influenza vaccination rate of patients and health care personnel and deleted language relative to how facilities will be assessed for the cost of program. The House voted **Ought to Pass with further Amendment**. The House amendment added back the requirements for tracking and reporting requirements for coverage rates for influenza vaccination rates but also added language making it clear that the bill does not mandate or require influenza vaccinations for health care workers or patients/residents in health care facilities. Senator Sanborn moved for non-concurrence. The Senate requested a Committee of Conference and no agreement was reached.

- SB 112: This bill requires Medicaid coverage under RSA-420-J to cover telemedicine services. The Senate voted **Ought to Pass with Amendment**. The amendment codifies the definition of telemedicine and the coverage requirement under the Medicaid statute rather than the insurance statute. The House voted **Ought to Pass with Amendment**. The amendment references CMS requirements of telehealth, conditions the section on approval of a Medicaid State Plan Amendment and establishes an advisory committee for implementation of Medicaid telehealth services. The bill was then referred to the Finance Committee. The Committee and full House voted **Ought to Pass with Amendment**. This amendment makes a slight wording change and also directs that the program shall commence on July 1, 2016, but not without approval of the fiscal committee of the general court by February 1, 2016, and requires the Department of Health and Human Services to report on the program's financial impact for its first six months by March 1, 2017. Senator Sanborn concurred with the House Amendments. It was **signed into law by the Governor on July 6** and effective upon signing.

- SB 133-FN: This bill requires certain encrypted health care information collected by the insurance department to be available to the public upon request to the Department of Health and Human Services under certain circumstances. Voted **Ought to Pass with Amendment** by the Senate Commerce Committee. The amendment adds language to include workers compensation medical claims data in the New Hampshire comprehensive health information system and to make such data available to the public. The House voted **Ought to Pass with Amendment**. The bill was then referred to the Labor, Industrial and Rehabilitative Services Committee where an amendment was introduced to require the Insurance Department to develop and publish a workers' compensation fee schedule. The full House voted **Ought to Pass with Amendment**, and Senator Sanborn concurred. That amendment deleted the requirement to make data available to the public and the requirement to develop and publish a workers' compensation fee schedule, instead providing simply that the Commissioner shall consult and make a report on options for including workers' compensation medical claims data in the New Hampshire comprehensive health information system on or before December 1, 2015. Significantly, the amendment also proposes to amend the workers' compensation law by providing that the employer shall pay the reasonable value of medical services provided and that the health care provider shall have the burden of establishing that its bill for services is reasonable. Under the proposal, if the payor and health care provider cannot resolve a dispute about the reasonable value of services, the Commissioner or its representative has exclusive authority to hold a hearing to resolve the issue. The bill was **signed into law by the Governor on July 6** and is effective on September 4, 2015.

~~*

Cinde Warmington and Benjamin Siracusa Hillman contributed to this month's Legal Update.

BIOS

CINDE WARMINGTON
Cinde, a partner at Shaheen & Gordon, leads the Health Care Practice Group and focuses her practice entirely on representing health care clients. Her prior clinical and administrative experience makes her uniquely qualified to assist providers in facing a rapidly changing regulatory environment.

BENJAMIN SIRACUSA HILLMAN
Ben assists individual practitioners, group practices, and hospitals with a variety of health related business, regulatory, and litigation issues, and advises small businesses on compliance with the Affordable Care Act. Ben also practices in the areas of civil litigation, elder law, estate planning and probate.