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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

HHS Reports that It Is Unable to Meet Court-Ordered Targets for Clearing Medicare Appeals Backlog

On March 5, the U.S. Department of Health and Human Services ("HHS") submitted its first status report to the U.S. District Court for the District of Columbia following the District Court's December 5 order compelling HHS to meet certain targets in reducing the Medicare appeals backlog. The American Hospital Association ("AHA") initially brought the action against HHS in 2014, seeking a writ of mandamus forcing HHS to take action to reduce the backlog of Medicare-reimbursement appeals. After more than two years of litigation, the District Court ordered HHS to reduce the current backlog of cases 30% by December 31, 2017, 60% by December 31, 2018, 90% by December 31, 2019, and 100% by December 31, 2020. The District Court also ordered HHS to file status reports every 90 days.

HHS's March 5 report is the first such status report. HHS reported that as of March 5 there were 667,326 pending appeals at the Office of Medicare Hearings and Appeals. The report states: "HHS projects the number of pending appeals to be 687,382 by the end of FY 2017 (September 30, 2017), 714,347 by the end of FY 2018 (September 30, 2018), 788,493 by the end of FY 2019 (September 30, 2019), 882,437 by the end of FY 2020 (September 30, 2020), and 1,009,768 by the end of FY 2021 (September 30, 2021)." These projections are greater than what were originally provided to the District Court, and HHS attributes the increase to several factors, including lower-than-expected participation by providers in a hospital settlement initiative. The report concludes that HHS will not be able to meet the District Court's reduction targets at current funding levels and without additional legislative authorities.

In January, the District Court rejected HHS's motion to reconsider the December 5 order, and on February 21 HHS filed an appeal of the decision to the Court of Appeals for the D.C. Circuit.

The District Court's December 5 order can be read here: https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2014cv0851-48.

HHS's March 5 status report can be read here: https://dlbjbjzgnk95t.cloudfront.net/0898000/898981/status.pdf.

CMS Post FAQs for Medicare Outpatient Observation Notice Requirement

On March 8, 2017, the Centers for Medicare & Medicaid Services ("CMS") posted a set of eight Frequently Asked Questions ("FAQs") about the Medicare Outpatient Observation Notice ("MOON") requirements for Medicare participating hospitals and critical access hospitals ("CAHs"). The MOON is mandated by the Federal Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act), which was passed on

August 6, 2015. The NOTICE Act requires all hospitals and CAHs to provide the MOON, which is a standardized notice to inform Medicare beneficiaries that they are outpatients receiving observation services and are not inpatients of a hospital or CAH.

The FAQs provide information about completing certain text fields in the standardized MOON provided by CMS and explains that hospitals and CAHs may only modify the MOON pursuant to certain CMS guidance. The FAQs also confirm that: the MOON requirement applies to psychiatric hospitals; hospitals and CAHs should translate the MOON pursuant to Section 1557 of the Affordable Care Act; and the MOON is required for Medicare Advantage enrollees in addition to Original Medicare (fee-for-service) enrollees.

Hospitals and CAHs were required to begin issuing the MOON as of March 8, 2017. The FAQs and additional information about the MOON requirement can be found at: https://www.cms.gov/Medicare/Medicare-General-information/Bni/index.html.

OIG Issues Favorable Advisory Opinion on Free or Discounted Meals and Lodging for Hospital Patients

On March 10, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") issued Advisory Opinion 17-01 concerning a hospital system's proposal to offer free or discounted meals and lodging to certain patients. Under the proposed arrangement, the hospital would provide free or discounted lodging to patients who live more than 90 miles from the hospital where they would be obtaining treatment, live in either a medically underserved area or a health professional shortage area, and whose household income does not exceed 500% of the Federal poverty level. The patient must also not be eligible for an inpatient stay at the hospital and have a follow-up appointment or survey within 48 hours to receive post-procedure lodging, and must be required to be at the hospital before 10 a.m. to receive pre-procedure lodging. Discounts would be provided on a sliding scale based on the patient's income. The hospital system expects that approximately 100-200 patients would qualify for this assistance each year.

OIG concluded that, while the provision of free or discounted lodging and meals would generally qualify as prohibited remuneration under the Anti-Kickback Statute ("AKS") and the Civil Monetary Penalties ("CMPs") for beneficiary inducements, the proposed arrangement nonetheless satisfies the Promotes Access to Care Exception to the CMPs, and OIG would not subject the hospital system to any civil or criminal penalties. OIG found that the proposed arrangement satisfied the two elements of the Promotes Access to Care Exception because: (1) it would promote access to care for Federal health care program beneficiaries by removing certain socioeconomic and geographic barriers to accessing care; and (2) it would present a low risk of harm to Federal health care programs and beneficiaries because it would be unlikely to interfere with clinical decision-making, it would be unlikely to increase costs to Federal health care programs, and it would not raise patient safety or quality-of-care concerns.

Advisory Opinion 17-01 can be read here: https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-01.pdf.

CMS Issues Final Enrollment Report for 2017 Open Enrollment

On March 15, the Centers for Medicare & Medicaid Services ("CMS") issued the "Health Insurance Marketplaces 2017 Open Enrollment Period Final Enrollment Report: November 1, 2016 – January 31, 2017," containing the final enrollment figures for 2017 Open Enrollment in the ACA Marketplaces. The Report shows that total enrollment in Marketplace plans fell from 12.7 million in 2016 to 12.2 million for 2017,

but does show that 31% of 2017 enrollments were new consumers. Of the total number of consumers who enrolled in Marketplace plans, approximately 83% qualified for advance payments of the premium tax credit ("APTC"), with an average value of $383 per person per month, which covered an average of 73% of the gross premium. For 2017, 71% of consumers enrolled in Silver plans, 21% enrolled in Bronze, 3% enrolled in Gold, 1% enrolled in Catastrophic, and less than 0.5% enrolled in Platinum plans.

The Final Enrollment Report can be read here: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-03-15.html.

HHS Issues Letter Encouraging States to Apply for ACA Innovation Waivers

On March 13, 2017, U.S. Department of Health and Human Services ("HHS") Secretary Thomas Price issued a letter to all 50 governors encouraging them to apply for Innovation Waivers available under Section 1332 of the Affordable Care Act ("ACA"). The letter was issued in accordance with President Trump's January 20, 2017 "Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal."

Section 1332 Innovation Waivers are meant to provide states with flexibility to implement innovative strategies to increase access to affordable, quality health care. The letter specifically cites high-risk pools and state-operated reinsurance programs as opportunities for states to lower premiums for consumers, improve market stability, and increase consumer choice, and cites a recent Alaska state-operated reinsurance initiative that is currently under review by HHS. The letter indicates that a state may be able to receive pass-through funding to help offset a portion of the costs for a high-risk pool or state-operated reinsurance program, and suggests that HHS will provide expedited review of waiver applications.

Secretary Price's letter can be read here: https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/March-13-2017-letter_508.pdf.

GOP Bill on Wellness Programs Clears House Committee

On March 8, H.R. 1313, the "Preserving Employee Wellness Programs Act," cleared the House Education and Workforce Committee in a 22-17 party-line vote. The bill, sponsored by Committee Chairwoman Virginia Fox (R-NC), would clarify that the collection of genetic information about employees participating in workplace wellness programs would not violate the Americans with Disabilities Act ("ADA") or the Genetic Information Nondiscrimination Act ("GINA"). Under GINA, employers may not collect and use employees' genetic information unless such information is provided voluntarily.

Since the bill's introduction in the U.S. House of Representatives on March 2, numerous politicians and organizations have come out against it, including AARP, the American Diabetes Association, and the American Academy of Pediatrics, many of which signed onto a March 8 opposition letter to Education and Workforce Committee leaders. Due to the significant discounts on health insurance premiums that employers can offer under the Affordable Care Act to employees who participate in workplace wellness programs, many critics argue that participation in such programs may be less than voluntary. Allowing employers to require genetic information as a requirement for participation, opponents argue, would result in the weakening of the anti-discrimination and privacy protections in the ADA and GINA.

The text of H.R. 1313 can be read here: https://www.congress.gov/bill/115th-congress/house-bill/1313/text.

The March 8 opposition letter to Education and Workforce Committee Leaders can be read here: https://www.c-c-d.org/fichiers/Preserving-Employee-Wellness-Act-letter-3-8-17.pdf.

OIG Modifies Advisory Opinion on Patient Assistance Programs

On March 10, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") issued a Notice of Modification of OIG Advisory Opinion No. 02-1. Advisory Opinion No. 02-1 ("AO 02-1") was a favorable opinion which concerned a nonprofit, tax-exempt, charitable organization ("Charity") providing cost-sharing and premium assistance to financially needy patients diagnosed with specific chronic illnesses and rare disorders. Following the issuance on May 21, 2014 of a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs ("Supplemental Bulletin"), the OIG sent a letter to the Charity highlighting certain features of its Patient Assistance Program ("PAP") were problematic and would need to be modified.

In its response to OIG's request, the Charity provided three certifications to address the concerns described in the Supplemental Bulletin: (1) the Charity will not define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease status; (2) the Charity will not maintain any disease fund that provides copayment assistance for only one drug or therapeutic device, or only the drugs or therapeutic devices made or marketed by one manufacturer or its affiliates; and (3) the Charity will not limit its assistance to high-cost or specialty drugs. The Charity also proposed some additional modifications to AO 02-1.

In addition to the certifications and modifications proposed by the Charity, OIG also required the Charity to make the following certifications to ensure compliance with its long-standing guidance regarding independence from donors: (1) the Charity's donors may earmark their contributions to a specific disease fund, but the donations are and will be otherwise unrestricted; (2) the Charity is and will be governed by an independent board of directors that will be free from donor influence; (3) the Charity, in its sole discretion, determines, and will determine, the diseases it supports through its funds; (4) the Charity certified that it assesses and will assess patient applications and makes grant determinations without regard to certain factors, including the interests of any donor; and (5) the Charity proposes to provide donors with quarterly or monthly projected estimates of when a particular fund is likely to be exhausted, based on current donations and assistance provided to fund enrollees.

OIGs Modification of AO 02-1 can be read here: https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn02-1-mod.pdf.

The original text of AO 02-1 can be read here: https://oig.hhs.gov/fraud/docs/advisoryopinions/2002/0201.pdf.

The Supplemental Bulletin can be read here: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf.

CMS Delays Effective Date of Mandatory Bundled Payment Models

On March 21, the Centers for Medicare & Medicaid Services ("CMS") issued an interim final rule delaying the effective date of the final rule entitled "Advancing Care Coordination Through Episode Payment Models ("EPMs"); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement ("CJR") Model" that was previously issued on January 3, 2017. The final rule's

previous effective date of March 21, 2017 has now been pushed back to May 20, 2017. The interim final rule also delays the applicability date of the regulations at 42 CFR part 512 from July 1, 2017 to October 1, 2017 and effective date of certain CJR regulations from July 1, 2017 to October 1, 2017. CMS is seeking comment on the appropriateness of this delay, as well as whether to further delay the final rule's effective date until January 1, 2018.

The final rule was originally scheduled to go into effect on February 18, 2017. As a result of a January 20 memorandum from Reince Priebus to the heads of executive department and agency heads entitled "Regulatory Freeze Pending Review," that date was pushed to March 21. The memorandum required executive departments and agencies to delay the effective date of any final rules published in the Federal Register to 60 days from January 20, and to consider delaying them even further, "for the purpose of reviewing questions of fact, law, and policy they raise."

The final rule implements three new Medicare Parts A and B EPMs and a Cardiac Rehabilitation ("CR") Incentive Payment model, and implements changes to the existing Comprehensive Care for Joint Replacement model. Under the three new episode payment models, acute care hospitals in certain selected geographic areas will participate in retrospective EPMs targeting care for Medicare fee-for service beneficiaries receiving services during acute myocardial infarction, coronary artery bypass graft, and surgical hip/femur fracture treatment episodes. All related care within 90 days of hospital discharge will be included in the episode of care. Under the CR Incentive Payment model, acute care hospitals in certain selected geographic areas will receive retrospective incentive payments for beneficiary utilization of cardiac rehabilitation/intensive cardiac rehabilitation services during the 90 days following discharge from a hospitalization treatment of an acute myocardial infarction or coronary artery bypass graft surgery.

The interim final rule was published in the Federal Register at 82 Fed. Reg. 14464, and can be read in its entirety at https://www.gpo.gov/fdsys/pkg/FR-2017-03-21/pdf/2017-05692.pdf.

U.S. House Cancels Vote on American Health Care Act

The United States House of Representatives was scheduled to hold a vote on the American Health Care Act ("AHCA") on Friday, March 24, but the bill was withdrawn at the last second by Speaker Paul Ryan. The AHCA – which was drafted by Speaker Ryan and promoted heavily by President Trump – was intended to repeal or replace those aspects of the Affordable Care Act ("ACA") affecting the Federal budget, including replacing premium subsidies with refundable tax credits and ending Medicaid expansion.

After significant public outcry over the Congressional Budget Office's prediction on March 13 that the bill would leave 24 million Americans without health insurance, moderate Republicans began to voice their dissatisfaction with the bill, prompting several rounds of revision. The bill was originally scheduled to go to a full vote on Thursday March 23, however opposition from the conservative House Freedom Caucus prompted additional last-minute changes, including the removal of the requirement that health plans provide coverage for certain "essential health benefits," including mental health and substance abuse treatment.

Ultimately, the bill failed to receive sufficient support from House Republicans, and it was pulled just minutes before the vote was scheduled to start. While President Trump and Speaker Ryan both indicated shortly after the bill was pulled that repealing and replacing the ACA was off the table for the foreseeable future, reports began to surface the following week that both the White House and House Republicans were open to re-engaging on the issue and trying to find a way to bridge the divide that resulted in the bill's initial failure.

Prior to the bill's eventual failure, NH Governor Chris Sununu had publicly stated his opposition to the bill in remarks made on March 14. Governor Sununu expressed disappointment in the bill's treatment of Medicaid, and highlighted the crucial role that expanded Medicaid in NH has played in the state's fight against opioid addiction.

HHS Delays Effective Date of Final Rule on 340B Program

On March 20, 2017 the Department of Health & Human Services ("HHS") published an interim final rule delaying the implementation of its earlier final rule on 340B civil monetary penalties ("CMPs") and ceiling prices. The rule was originally meant to be effective on March 6, however a subsequent final rule was published on March 6 further delaying the rule's effective date to March 21, in accordance with the White House January 20, 2017 memorandum entitled ''Regulatory Freeze Pending Review.'' This most recent rule pushes the effective date out to May 22, and invites comments on whether to delay that date further to October 1, 2017.

The rule applies to all drug manufacturers that are required to make their drugs available to covered entities under the 340B program and provides the calculation of the 340B ceiling price and the appropriate application of civil monetary penalties (CMPs).

Under the final rule, a drug manufacturer that "knowingly and intentionally" overcharges a 340B covered entity may be fined up to $5,000 for each instance of overcharging. The rule further permits a manufacturer to sell a drug at $0.01 if the ceiling price calculation results in a price of $0.00, and requires manufacturers to offer refunds for overcharges on new drugs.

The final rule also provides authority to the HHS Office of Inspector General (OIG) to bring 340B actions. "[A]s a general principle, HHS will defer to OIG to determine whether a given situation constitutes a 'knowing and intentional' 340B drug overcharge based on the specific case being investigated," the rule said.

The text of the original rule, published on January 5, 2017, can be read here: https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf.

The text of the interim final rule delaying the effective date, published on March 20, 2017, can be read here: https://www.gpo.gov/fdsys/pkg/FR-2017-03-20/pdf/2017-05526.pdf.

FDA Delays Effective Date of Final Rule on Off-Label Communications

On March 20, 2017, the Food and Drug Administration ("FDA") published an interim final rule further delaying the effective date of a final rule on off-label communications that was published in the Federal Register on January 9. The effective date was previously delayed until March 21, 2017, and is now further delayed until March 19, 2018.

The rule amends FDA regulations on the "intended use" of a product to clarify that the FDA does not, absent extraordinary circumstances, regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on that firm's knowledge that the product was being prescribed or used by doctors for such use.

FDA's stated reason for this recent delay is a petition it received from affected parties which raises

questions about the amendments to the regulations regarding ‘‘intended uses’’ and requests that FDA reconsider these amendments. Among the petitioners’ complaints are: (1) the final rule was promulgated in violation of the fair notice requirement under the Administrative Procedure Act; (2) the ‘‘totality of the evidence’’ standard for evaluating compliance established in the final rule is a new and unsupported legal standard; and (3) the revisions to the intended use regulations run contrary to ‘‘the settled interpretation’’ of intended use.

FDA is further delaying the effective date to invite public comment on the important substantive issues raised by the petition and to allow additional time to fully evaluate these issues and any other issues raised in response to this request for comments.

The text of the original rule, published on January 9, 2017, can be read here: https://www.gpo.gov/fdsys/pkg/FR-2017-01-09/pdf/2016-31950.pdf.

The text of the petition to the FDA can be read here: https://www.regulations.gov/document?D=FDA-2015-N-2002-1977.

The text of the recent interim final rule can be read here: https://www.gpo.gov/fdsys/pkg/FR-2017-03-20/pdf/2017-05526.pdf.

HHS Publishes Final Rule on Hospital-Specific Limits for Medicaid DSH Payments

On April 3, 2017, the U.S. Department of Health and Human Services, Center for Medicare & Medicaid Services (“CMS”) published a final rule on the application of the hospital-specific limitations on Medicaid disproportionate share hospital (“DSH”) payments.

The rule makes explicit in the text of the regulation an existing interpretation that uncompensated care costs include only those costs for Medicaid eligible individuals that remain after accounting for payments made to hospitals by or on behalf of Medicaid eligible individuals, including Medicare and other third party payments that compensate the hospitals for care furnished to such individuals. As a result, the hospital-specific limit calculation will reflect only the costs for Medicaid eligible individuals for which the hospital has not received payment from any source.

The rule notes that many commenters suggested that CMS’ interpretation of the hospital-specific limit is inconsistent with the statutory language under the Social Security Act (the “Act”), or that CMS’ interpretation is not required under the Act. CMS responded that language in the Act that the costs of providing services are “as determined by the Secretary” gives it the discretion to take Medicare and other third party payments into account when determining a hospital’s costs for the purpose of calculating Medicaid DSH payments.

The final rule was published three weeks after the New Hampshire Hospital Association (“NHHA”) obtained a ruling in Federal court that bars CMS from using language from sub-regulatory guidance – such as Frequently Asked Questions (“FAQs”) – to determine the amount owed to hospitals. Prior to the final rule and the court’s ruling, CMS relied on language in the FAQs stating that DSH payments would be calculated by taking into account payments hospitals received from Medicare and other third party payers. The court agreed with the NHHA that the calculation of DSH payments must be made based on criteria listed in regulations finalized through notice and comment rulemaking.

The text of the final rule can be read here: https://www.gpo.gov/fdsys/pkg/FR-2017-04-03/pdf/2017-06538.pdf

CMS Posts Forms for Stark Self-Referral Disclosure

On March 27, 2017, the U.S. Department of Health and Human Services, Center for Medicare & Medicaid Services ("CMS") revised the CMS Voluntary Self-Referral Disclosure Protocol ("SRDP") involving noncompliance with the Stark prohibition on physician self-referrals.

Part of the revision includes the introduction of standardized forms for use in disclosing actual or potential violations. Beginning on June 1, 2017, providers must complete and submit a packet of four forms: (1) an SRDP Disclosure form; (2) Physician Information Form(s); (3) a Financial Analysis Worksheet; and (4) a certification verifying the accuracy of the information.

Section 6409 of the Patient Protection and Affordable Care Act required the Secretary of the Department of Health and Human Services, in cooperation with the Inspector General of the Department of Health and Human Services, to establish a Medicare self-referral disclosure protocol that sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute. According to CMS, as of February 28, it has received 882 disclosures under the SRDP, 244 of which settled, 99 that withdrew or closed without administrative resolution, and 143 that are currently under active review.

The revised SRDP and new standard forms can be found here: https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/self_referral_disclosure_protocol.html#sthash.NFHmold3.dpuf

CMS Issues Memo Urging Providers to Satisfy the Training and Testing Requirements of Emergency Preparedness Rule

On March 24, 2017, the U.S. Department of Health and Human Services, Center for Medicare & Medicaid Services ("CMS") published a memo providing information to assist providers and suppliers in meeting the new training and testing requirements of the Emergency Preparedness Requirements for Medicare & Medicaid Participating Providers and Suppliers Final Rule. The final rule was effective on November 15, 2016 and has an implementation date of November 15, 2017. The memo clarifies that as of November 15, 2017, providers and suppliers are expected to meet the requirements of the training and testing program.

In order to meet these requirements, CMS strongly encourages providers and suppliers to seek out and to participate in a full-scale, community-based exercise with their local and/or state emergency agencies and health care coalitions and to have completed a tabletop exercise by the implementation date. The memo recognizes that some providers and suppliers are waiting for the release of further interpretive guidance from CMS before planning these exercises, but the memo states that this is not necessary nor is it advised. Providers and suppliers that are found to have not completed these exercises, or any other requirements of the final rule upon their survey, will be cited for non-compliance.

The text of the memo can be read here: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-21.pdf

HHS Publishes Compliance Program Resource Guide

On March 27, 2017, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") published "Measuring Compliance Program Effectiveness – A Resource Guide." The Resource Guide is the product of a roundtable meeting held on January 17 by a group of compliance professionals and OIG staff. During the meeting, the attendees broke into groups to discuss various areas of an effective compliance program and brainstorm individual compliance program metrics for the seven Compliance Program Elements from the Health Care Compliance Association's "CHC Candidate Handbook: Detailed Content Outline":

1. Standards, Policies, and Procedures
2. Compliance Program Administration
3. Screening and Evaluation of Employees, Physicians, Vendors and other Agents
4. Communication, Education, and Training on Compliance Issues
5. Monitoring, Auditing, and Internal Reporting Systems
6. Discipline for Non-Compliance
7. Investigations and Remedial Measures

The Resource Guide compiles the many individual compliance program metrics for each element for use by health care organizations in creating and administering effective compliance programs. The purpose of the list of metrics is to give health care organizations as many ideas as possible, be broad enough to help any type of organization, and let the organization choose which ones best suit its needs.

The Resource Guide can be read here: https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf.

HHS Delays Effective Date of HHA Conditions of Participation

On April 3, 2017, the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS") published a proposed rule that would move the effective date of an earlier final rule on the Conditions of Participation ("COPs") for home health agencies ("HHAs") from the current effective date of July 13, 2017 to January 13, 2018.

The final rule revised the COPs that HHAs must meet in order to participate in the Medicare and Medicaid programs. The requirements focus on the care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements.

Since the final rules was published on January 13, 2017, CMS received inquiries that represented a large number of HHAs requesting that the agency delay the effective date for the new COPs because HHAs were not able to effectively implement the new COPs until CMS issued its revised Interpretive Guidelines. In addition, one of the inquiries stated that HHAs were unable to effectively implement the new COPs until CMS issued further sub-regulatory guidance related to converting subunits to branches or independent HHAs, which would impact 216 HHAs nationwide. CMS is proposing to delay the effective date an additional six months to January 13, 2018 in order to address these concerns.

CMS is seeking comments on the proposed delay; comments are due by June 2.

The text of the April 3 proposed rule can be read here: https://www.gpo.gov/fdsys/pkg/FR-2017-04-03/pdf/2017-06540.pdf.

The text of the January 13 final rule can be read here: https://www.gpo.gov/fdsys/pkg/FR-2017-01-13/pdf/2017-00283.pdf.

STATE DEVELOPMENTS

NH House Fails to Pass Budget Legislation

For the first time in decades the NH House of Representatives was unable to pass a budget bill (HB1) when a coalition of Republicans and Democrats joined together to defeat the legislation. The responsibility for developing the budget will now move to the Senate which will consider amendments to the proposed budget submitted by Governor Sununu. Under the New Hampshire constitution, all budget bills must originate in the House, as a result, the Senate will now amend a House bill that has crossed-over to the Senate to add the Senate's version of the budget. The Senate's budget will then be presented to the House where it will likely vote not to concur and request a Committee of Conference. Representatives from both parties will then work to find a compromise budget. The failed HB1 would have appropriated $14 Million less towards the State Medicaid shortfall than the Governor's budget.

2017 NH Physician Licensure Survey

The NH Division of Public Health Services (DPHS) is collecting data regarding physician provider status and practice locations. Only physicians due to renew their medical licenses in 2017 must access the survey. DPHS reports that the data collected will be used as a resource for statewide health access planning, workforce assessment, educational and training programs, emergency preparedness, recruitment and retention initiatives, and other functions requiring data on provider capacity. It is estimated the survey takes 3-15 minutes to complete. The physician responses are confidential and protected.

The survey may be accessed at https://nhprovidersurvey.co1.qualtrics.com

On March 15, the Board of Medicine advised that renewal application for physicians whose licenses expire on June 30, 2017 have been mailed.

2017 Legislative Updates

We are currently tracking the following Bills:

HB 157: This bill adds chronic pain to the qualifying medical conditions under therapeutic use of cannabis. **Status: Voted Ought to Pass with Amendment by the House. Amendment removes the requirement that a patient with chronic pain also experience one of the qualifying symptoms listed in the statute. Introduced in Senate and referred to Senate HHS Committee.**

HB 158: This bill adds opioid addiction to the qualifying medical conditions under therapeutic use of cannabis. **Status: Voted Inexpedient to Legislate by the House.**

HB 159: This bill adds fibromyalgia to the qualifying medical conditions under therapeutic use of cannabis. **Status: Voted Inexpedient to Legislate by the House.**

HB 160: This bill adds post-traumatic stress disorder to the qualifying medical conditions under therapeutic use of cannabis. **Status: Voted Ought to Pass with Amendment by the House. Amendment removes the requirement that a patient with post-traumatic stress disorder also experience one of the qualifying symptoms listed in the statute. Introduced in Senate and referred to Senate HHS Committee.**

HB 162: This bill establishes a procedure for the annulment of a mental health record. **Status: Voted Inexpedient to Legislate by the House.**

HB 184-FN: This bill repeals RSA 328-J, the regulation of medical imaging and radiation therapy under the board of medical imaging and radiation therapy. **Status: Voted Ought to Pass by the House and Senate. Bill was amended by the House to change the bill from a repeal of the license requirement to an extension of the enactment date of the license requirement from July 1, 2017 to July 31, 2018.**

HB 197: This bill adds myelitis disorder or disease to the qualifying medical conditions under therapeutic use of cannabis**. Status: Voted Inexpedient to Legislate by the House.**

HB 200: This bill authorizes heath care facilities and physicians to dispense medication and use equipment and therapies which are not Food and Drug Administration approved. **Status: Voted Inexpedient to Legislate by the House.**

HB 208: This bill establishes a commission to study current mental health procedures for involuntary commitment. **Status: Voted Out to Pass with Amendment by the House and Senate. Amendments changed the composition of the commission.**

HB 222: This bill makes certain changes to the law regarding use of cannabis for therapeutic purposes, including broadening the definition of "qualifying medical condition." **Status: Voted Inexpedient to Legislate by the House.**

HB 250: This bill establishes a commission to study the benefits and costs of a "health care for all" program for New Hampshire. **Status: Voted Ought to Pass with Amendment by the House. Amendment reduces commission from 16 members to 5 and adds additional questions for study. Introduced in Senate and referred to Senate Commerce Committee.**

HB 256: This bill authorizes a person to self-order laboratory testing without a health care provider's request under certain circumstances. **Status: Voted Inexpedient to Legislate by the House.**

HB 291: This bill removes the requirement that the board of veterinary medicine adopt rules regarding prescribing opioids and that veterinarians query the controlled drug prescription monitoring program when prescribing such drugs. **Status: Voted Ought to Pass with Amendment by the House. Amendment did not substantially change the bill. Introduced in Senate and referred to Senate HHS Committee.**

HB 295: This bill repeals the prohibition against assigning medical payments under motor vehicle liability policies to health care providers. **Status: Voted Inexpedient to Legislate by the House.**

HB 321: This bill establishes a commission to study a public option program for health insurance in New Hampshire. **Status: Voted Inexpedient to Legislate by the House.**

HB 322: This bill declares that certain licensing boards for health care providers may adopt rules to require completion of a certain survey as part of the license renewal process. This bill is a result of the commission established in 2016, 252. **Status: Voted Ought to Pass by the House. Introduced in Senate and referred to Senate Executive Departments and Administration Committee.**

HB 329: This bill establishes a committee to study balance billing by health care providers. **Status: Voted Ought to Pass by the House; voted Ought to Pass with Amendments by the Senate. Amendment changes the committee's composition from 3 representatives and 2 senators to 4 representatives and 1 senator. Non-germane amendment adds an authorization for municipal ratification of town meetings and elections that were rescheduled due to March 14 snowstorm.**

HB 334: This bill exempts from licensure by the board of medical imaging and radiation therapy persons who perform sonography in certain circumstances. **Status: Voted Ought to Pass with Amendment by the House. Amendment changes the exemption to an exemption from licensure for any "person who is regulated in another profession [and] acting within the scope of that person's license, registration, or certification." Introduced in Senate and referred to Senate Executive Departments and Administration Committee.**

HB 361: This bill deletes the authority of the commissioner of the department of health and human services to adopt rules regarding certain child immunizations/vaccines. **Status: Voted Inexpedient to Legislate by the House.**

HB 362: This bill declares that immunization/vaccine requirements shall not be established for diseases that are noncommunicable in a child care or school setting, including hepatitis B. **Status: Voted Ought to Pass with Amendment by the House; voted Ought to Pass by Senate HHS Committee. Amendment limits the exemption simply to diseases that are noncommunicable, without regard to setting.**

HB 442: This bill prohibits employers from asking a job applicant about his or her criminal history prior to an interview. **Status: Voted Inexpedient to Legislate by the House.**

HB 443: This bill prohibits prescription drug manufacturers from offering to pay or reimburse an individual for his or her insurance copayment. **Status: Voted Inexpedient to Legislate by the House.**

HB 455-FN: This bill prohibits pharmacy benefit managers from requiring providers to attain accreditation, credentialing, or licensing other than by the pharmacy board or other state or federal entity. **Status: Voted Ought to Pass by the House. Introduced in Senate and referred to Senate Commerce Committee.**

HB 468-FN: This bill allows persons licensed as mental health practitioners in other states to practice in this state 60 days after application to the board of mental health practice, pending final approval. **Status: Voted Ought to Pass by the House; voted Ought to Pass with Amendment by the Senate Executive Departments and Administration Committee. Amendment did not substantively change the bill.**

HB 469: This bill requires licensed pharmacies to establish continuous quality improvement programs to identify weaknesses in processes and systems and make appropriate corrections. This bill is a request of the pharmacy board. **Status: Voted Ought to Pass by the House. Introduced in Senate and referred to Senate HHS Committee.**

HB 471-FN: This bill requires the department of health and human services to publish an annual report consisting of an aggregate statistical summary of all induced terminations of pregnancy performed in New Hampshire. This report shall be available to the public. Data submitted by providers shall be for statistical purposes only and not public records. **Status: Retained in House HHS Committee.**

HB 472: This bill permits qualifying patients and registered caregivers to cultivate cannabis for therapeutic use. **Status: Voted Ought to Pass by the House. Introduced in Senate and referred to Senate HHS Committee.**

HB 510: This bill declares that with the insured's permission, medical payments under a motor vehicle liability policy may be assignable to a health care provider. **Status: Voted Inexpedient to Legislate by the House.**

HB 511: This bill establishes a commission to study creating a public health oversight program within the department of health and human services. **Status: Voted Ought to Pass with Amendment by the House. Amendment adds members to the commission and increases the scope of its study. Introduced in Senate and referred to Senate HHS Committee.**

HB 572-FN: This bill extends the suspension of prior authorization requirement for a community mental health program on drugs used to treat mental illness. **Status: Retained in House Finance Committee.**

HB 575-FN: This bill allows the board of acupuncture to certify individuals as acupuncture detoxification specialists. **Status: Voted Ought to Pass with Amendment by the House. Amendment clarifies requirements for board certification. Introduced in Senate and referred to Senate Executive Departments and Administration Committee.**

HB 578-FN: This bill prohibits an abortion of a viable unborn child, except in cases of medical emergency. **Status: Laid on table by the House.**

HB 589-FN: This bill repeals the law relative to providing certain parameters for access to reproductive health care facilities. **Status: Voted Inexpedient to Legislate by the House.**

HB 596-FN: This bill permits a person who has been involuntarily committed to a treatment facility under RSA 135-C to request a review hearing every 2 years. **Status: Retained in House Judiciary Committee.**

HB 602-FN-A: This bill prohibits the placement of certain persons with mental illness in the secure psychiatric unit. The bill establishes a commission to develop plans and oversee the establishment of a secure psychiatric hospital to treat such persons who would present a serious likelihood of danger to themselves or others. This bill also makes an appropriation for the purposes of the bill. **Status: Voted Inexpedient to Legislate by the House.**

HB 606-FN-A: This bill establishes a scholarship fund for health care providers who stay in New Hampshire for 5 years and makes an appropriation therefor. **Status: Voted Inexpedient to Legislate by the House.**

HB 611: This bill clarifies premium rates for individuals and small employers under the law relating to portability, availability and renewability of health care coverage. **Status: Voted Inexpedient to Legislate by the House.**

HB628-FN: This bill establishes a system of paid family and medical leave insurance. **Status: Retained in House Labor Committee.**

HB 630-FN-A: This bill establishes the state health information and analysis program. Under this bill, the commissioner of the department of health and human services, the insurance commissioner, the commissioner of the department of corrections, and the attorney general shall enter into a memorandum of understanding to collaborate in the development of publicly available information on health care system patient safety, cost, quality, access to coverage and care, system performance, and efficiency and information pertaining to the delivery and financing of the health care system in New Hampshire, including information on new health system projects and associated costs. The bill establishes a health information and analysis planning council to provide consultation for the development of a public data resource for New Hampshire. The bill also establishes a fund for the implementation and administration of the requirements of the program. **Status: Retained in House HHS Committee.**

HB 633-FN: This bill allows health insurance policies without mandates to be sold to New Hampshire residents. Under this bill, if the policy or certificate does not include certain mandated coverages, it must be submitted to the insurance commissioner for approval. **Status: Voted Inexpedient to Legislate by the House.**

HB 638-FN-LOCAL: This bill repeals the New Hampshire health protection program. **Status: Voted Inexpedient to Legislate by the House.**

HB 650-FN: This bill makes various changes to the regulation of psychology practitioners including the requirements of the board of psychologists relating to investigation and hearings concerning disciplinary proceedings, the form of complaints against licensees, and the disclosure of patient records. **Status: Voted Ought to Pass with Amendment by the House. Voted Ought to Pass with Amendment by Senate Executive Departments and Administration Committee. Senate Amendment adds procedural requirements for board hearings.**

SB 15: This bill adds a new qualifying medical condition for the purposes of receiving cannabis for therapeutic use**,** severe pain that has not responded to previously prescribed medication or surgical measures or for which other treatment options produced serious side effects. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass by House HHS Committee.**

SB 17: This bill clarifies hepatitis C as a qualifying medical condition for the use of cannabis for therapeutic purposes. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass by House HHS Committee.**

SB 26: This bill clarifies the definition of "facility caregiver" for purposes of the use of cannabis for therapeutic purposes law to include community living facilities certified under RSA 126-A:19 and RSA 126-A:20. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass by House HHS Committee.**

SB 54: This bill increases the number of hours of alcohol and drug use education required for initial licensure as a master license alcohol and drug counselor or as a licensed alcohol and drug counselor. **Status: Laid on Table by Senate.**

SB 59: This bill creates a process for certain individuals to request a blood testing order when they have been exposed to a source individual's bodily fluids. **Status: Voted Ought to Pass with Amendment by**

Senate. Voted Ought to Pass with Amendment by House HHS Committee. Amendments clarify the bill's applicability to nurses, physicians and physician assistances, individuals who give aid at the scene of an emergency, require private insurance to pay for such testing for those not covered by workers compensation, and also make other non-substantive changes.

SB 61: This bill clarifies the procedure for receipt of medical records of a deceased spouse or next of kin. **Status: Voted Ought to Pass with Amendment by Senate. Voted Ought to Pass with Amendment by House HHS Committee. Amendments clarify criteria for determining who may receive a deceased individual's medical records and how.**

SB 65: This bill adds certain vaccines to the law which allows licensed pharmacists to administer vaccines including hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccines. **Status: Voted Ought to Pass by Senate. Introduced in House and referred to House HHS Committee.**

SB 126: This bill requires the public utilities commission to award funds from the renewable energy fund to hospitals with renewable energy projects. **Status: Voted Ought to Pass by Senate. Introduced in House and referred to House Science, Technology and Energy Committee.**

SB 139: This bill modifies the requirements for licensure of magnetic resonance technologists by the board of medical imaging and radiation therapy. **Status: Voted Inexpedient to Legislate by Senate.**

SB 144-FN: This bill clarifies the definition of "qualifying medical condition" to include certain conditions which trigger certain medical symptoms. This bill also deletes the requirement that a medical provider document how the injury affects activities of daily living. **Status: Voted Ought to Pass with Amendment by Senate. Voted Ought to Pass with Amendment by House HHS Committee. Amendments clarify the statements signed by applicants for a registry identification card.**

SB 146-FN: This bill requires the commissioner of the department of health and human services to develop a centralized state system for transporting persons subject to involuntary emergency admission. This bill is a result of the committee established in 2016, 101. **Status: Senate laid on table.**

SB 149: This bill authorizes individuals and certain businesses to purchase health insurance from out-of-state companies. The bill grants rulemaking authority to the insurance commissioner for the purposes of the bill. **Status: Senate laid on table.**

SB 150: Under this bill, a pharmacy intern under the direct supervision of a pharmacist may administer immunizing vaccines. **Status: Voted Ought to Pass by Senate. Introduced in House and referred to House HHS Committee.**

SB 151: This bill prohibits a nursing facility from requiring that a patient sign a mandatory arbitration agreement. **Status: Introduced and referred to Senate HHS Committee. Rereferred to committee.**

SB 152: This bill allows for temporary employment in a residential care facility or as a licensed nursing assistant by persons awaiting the results of a criminal history background check. **Status: Voted Ought to Pass with Amendment by Senate. Voted Ought to Pass with Amendment by House HHS Committee. Amendments impose additional restrictions on the temporary license.**

SB 154: This bill allows pharmacies to dispense oral contraceptives to persons 18 years of age or older without a prescription. **Status: Introduced and referred to Senate HHS Committee. Rereferred to committee.**

SB 155: This bill declares that step 2 of the Medicaid managed care program shall not be implemented until July 1, 2019. **Status: Voted Ought to Pass with Amendments by Senate. Introduced in House and referred to House HHS Committee. Amendments (1) carve out nursing facility services and services provided under the choices for independence waiver for implementation on January 1, 2019, and (2) clarify that the remaining provisions of step 2 "shall not be implemented before July 1, 2019."**

SB 156: This bill clarifies the process of paying for filling prescriptions for covered persons. The bill also adds authority for the pharmacy board to adopt rules for enforcement of requirements for the price of filling prescriptions. **Status: Voted Inexpedient to Legislate by Senate.**

SB 157: This bill adds rulemaking for persons with substance use disorder for the purposes of the managed care law. This bill also requires health carriers to notify covered persons of their rights as a managed care consumer. **Status: Voted Ought to Pass with Amendments by Senate. Introduced in House and referred to House HHS Committee. Amendments alter the language of the consumer rights notification.**

SB 158: This bill declares that if substance use disorder services are a covered benefit under a health benefit plan, no prior authorization shall be required for prescribed medications for a substance use disorder. **Status: Voted Ought to Pass with Amendment by Senate. Introduced in House and referred to House HHS Committee. Amendment changes authorization renewal frequency from once very 24 months to once very 12 months.**

SB 159: This bill adds Ehlers-Danlos syndrome to the definition of "qualifying medical conditions" for the purposes of therapeutic cannabis. **Status: Voted Ought to Pass by Senate. Introduced in House and referred to House HHS Committee.**

SB 189-FN: This bill requires insurance policies to cover 3-D tomosynthesis mammography. **Status: Introduced and referred to Senate Commerce Committee. Rereferred to committee.**

SB 212: This bill adopts the physical therapy licensure compact, implemented by the physical therapy governing board. **Status: Voted Ought to Pass by Senate. Introduced in House and referred to House Executive Departments and Administration Committee.**

SB 220-FN: This bill changes the definition of mental illness for the purpose of involuntary commitment to include ingestion of opioid substances. **Status: Introduced and referred to Senate HHS Committee. Rereferred to committee.**

SB 236: This bill makes the Medicaid expansion law permanent. The program would currently expire December 31, 2018. **Status: Senate laid on table.**

SB 237-FN: This bill allows medical providers who practice in metropolitan areas to be reimbursed by Medicaid for telehealth services. **Status: Voted Ought to Pass by Senate. Introduced in House and**

referred to House HHS Committee.

SB 238-FN: This bill clarifies the term "usual and customary price" for the purposes of filling prescriptions to mean the price an individual would pay for a prescription at a retail pharmacy if that individual did not have a prescription drug benefit or insurance. **Status: Voted Ought to Pass by Senate. Introduced in House and referred to House HHS Committee.**

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Cinde Warmington, Kara J. Dowal, S. Amy Spencer and Alexander W. Campbell contributed to this month's Legal Update.

BIOS

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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.

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