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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

Affordable Care Act Implementation

Supreme Court Hears Oral Argument in Case Challenging Provision of Premium Tax Credits to Enrollees in Federal Exchanges

On March 4, the Supreme Court heard oral argument in *King v. Burwell*, in which plaintiffs are challenging the availability of tax subsidies for enrollees in the federal health insurance marketplaces. The case is the most serious challenge to the Affordable Care Act since the 2012 Supreme Court decision upholding it, although a win for the plaintiffs would still leave untouched many significant parts of the law, such as Medicaid expansion, health insurance regulations, and new taxes.

Court watchers generally agreed that the Court seemed split, with the fate of the subsidies hanging on the votes of Justices Kennedy and Roberts, who did not make their views clear. A decision in favor of the challengers would have far-reaching implications for the individual insurance marketplaces in those states that use the federal marketplace, including New Hampshire. Health economists say that such a decision could have destabilizing effects on the individual health insurance market generally, even for those not receiving subsidies, and would lead, at a minimum, to the loss of health insurance for many of those now purchasing insurance through the individual market and to significant price hikes for remaining individual purchasers of health insurance starting in 2016. A decision is expected in June.

Healthcare.gov Glitch Sends Wrong Tax Information to 800,000 People

The Federal government recently announced that inaccurate tax filing information about health insurance subsidies was sent to 800,000 Americans who purchased coverage through Healthcare.gov last year. Individuals who had already filed their returns using the erroneous forms are not required to file amended returns, although they may wish to do so if the revised data results would result in a refund.

Healthcare.gov Reopening for Special Enrollment Period from March 15 through April 30

In response to many individuals discovering for the first time when they filed their 2014 tax returns that they owed a penalty for not having had health insurance in 2014, the federal government announced that the health insurance marketplace would feature a special enrollment period to run from March 15 through April 30. This enrollment period is open to individuals who are not currently enrolled in marketplace coverage for 2015, who paid a shared responsibility payment with their 2014 federal income tax return as a result of not having had health coverage in 2014, who state that they were confused or did not know about the open enrollment dates for 2015 coverage, and need another opportunity to enroll in coverage for the remainder of 2015. Ordinarily, individuals may only enroll in coverage

through the marketplace during open enrollment or when they experience a qualifying event such as a marriage, divorce, birth of a child, change in income that affects eligibility for subsidies, or loss of health insurance coverage.

OIG Announces Plan for Health Reform Oversight

On February 24, the OIG released its "Health Reform Oversight Plan" for FY 2015, which describes the OIG's current and planned efforts to oversee the implementation and management of HHS programs under the Affordable Care Act. The plan outlines the OIG's key tactical considerations; key focus areas, both in the health insurance marketplaces and in other ACA-related HHS programs; and target timeframes for issuing reports on reviews related to the marketplace. While the report focuses on audits and evaluations, the OIG notes that it is also prepared for and engaged in law enforcement operations related to ACA programs. Beyond the health-insurance marketplaces, the OIG said the ACA-based reviews in FY 2015 would include evaluating the expansion of the Medicaid program; examining Medicare's transition to a value-based payment system, such as in the Pioneer Accountable Care Organization program; and examining the effectiveness of the ACA's program integrity tools, such as enhanced provider screening, payment suspensions and the Open Payments program.

Other Federal Developments

Report Finds Medicare and Medicaid Are Among Government's High-Risk Programs

On February 11, the Government Accountability Office (GAO) released its biennial High Risk Series report, in which it identified 32 federal programs at high risk for fraud, waste and abuse. The Medicare and Medicaid programs made the list again this year. Medicare has been designated a high-risk program since the first year the report was published in 1993; Medicaid was added to the list in 2003. While the report found that CMS has made improvements to reduce improper payments, it also found that Medicare reported an estimated $60 billion in improper payments in 2014. The GAO sets forth several recommendations for CMS to reduce these improper payments, including, for example, "CMS could establish core elements for provider and supplier compliance programs; ensure that the database used to track Recovery Auditors' (RA) activities includes complete and accurate data; and address the identity theft risks associated with having Social Security numbers on Medicare beneficiaries' health insurance cards." In addition to the Medicare and Medicaid programs, this year's report also added information technology acquisitions and operations and Veterans Affairs health care to the list. In order to be removed from the GAO's report, the programs must satisfy the following five criteria: (1) leadership commitment, (2) agency capacity, (3) an action plan, (4) monitoring efforts, and (5) demonstrated progress.

CMS Paid $10.7 Million to Providers with Delinquent Medicare Debts

On February 18, the OIG released a report finding that CMS made $10.7 million in Medicare and Medicaid reimbursements to physicians with delinquent debts after CMS had referred their Medicare debts to the U.S. Department of Treasury for collection. Specifically, CMS directly paid five individual physicians after referring their Medicare debts to the Treasury, and 21 individual physicians provided services for an entity that received Federal reimbursement. The OIG found that CMS made these payments because individual physicians' debts were associated with their individual provider numbers, not the provider numbers associated with the entities under which they performed services; and entities for which individual physicians with delinquent debts have an ownership interest and/or managing control are currently not always precluded from enrolling in Medicare. A final rule that was released in December 2014 – after the report was

completed – would prevent entities from enrolling in Medicare if any of their owners had Medicare debts. The OIG recommended that CMS take a series of steps to ensure that it does not pay individual physicians with delinquent debts and CMS concurred.

CMS Completes End-to-End Testing of New ICD-10 Coding

In a February 25 blog post, CMS Administrator Marilyn Tavenner announced that CMS recently conducted a week of end-to-end testing of ICD-10 claims, during which 660 providers and billing companies submitted 15,000 test claims using ICD-10 coding. Testing participants included health-care providers, billing firms and equipment suppliers. Overall, CMS found that the participants were able to successfully submit ICD-10 claims through CMS's billing systems. Additional testing weeks are scheduled for April and July ahead of the October 1 ICD-10 implementation date. CMS also clarified that when ICD-10 takes effect, providers will be required to use ICD-9 codes on claims for any services provided before the conversion date, even if they are submitted after October 1.

This testing period followed the release of a GAO report entitled "CMS' Efforts to Prepare for the New Version of the Disease and Procedure Codes." While the GAO highlighted CMS's broad efforts to educate providers and conduct limited testing, the agency called attention to the fact that while all Medicaid agencies reported that they would be able to perform all of the activities that CMS has identified as critical by the October 1 transition deadline, not all agencies have started to test their systems' abilities to accept and adjudicate claims containing ICD-10 codes.

CMS Extends Meaningful Use Attestation Deadline

On February 25, CMS announced that it is extending the deadline for eligible professionals to attest to meaningful use for the Medicare Electronic Health Record (EHR) Incentive Program 2014 reporting year. The new deadline is 11:59 p.m. ET on March 20. The extended deadline also applies to the EHR reporting option for the Physician Quality Reporting System (PQRS). The extension does not affect deadlines for the Medicaid EHR Incentive Program; however, it allows eligible professionals who have not used their one switch to go from Medicare to Medicaid or vice versa more time to do so for the 2014 year. The original deadline for attestation was February 28.

CMS Delays Publishing Final Rule on Repaying Medicare Overpayments for One Year

In a notice published on February 17, CMS announced a one-year delay in the publication of a final rule that will require providers to repay Medicare overpayments within 60 days of discovering them. CMS published a proposed rule three years ago, on February 26, 2012. The final rule was scheduled to be published in February 2015 to meet the requirement that final rules be published within three years of publication of a proposed or interim final rule. CMS reported that in this case, "the complexity of the rule and scope of comments" warrant the extension of time for publication. The notice makes clear that even without a final rule in place, providers still face penalties and potential False Claims Act liability for failing to return Medicare overpayments. In addition to addressing how quickly providers and suppliers have to repay identified Medicare overpayments, the final rule would also establish a look-back period.

CMS Corrects 2015 Medicare Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Final Rule

On February 24, CMS published a notice correcting its November 10, 2014 final rule updating the OPPS and ASC Payment System rates and policies for 2015. In addition to fixing various technical errors, the notice increases the OPPS conversion factor from $74.144 to $74.173, which will slightly increase

payment rates for most ambulatory payment classifications. However, CMS is reducing the 2015 ASC conversion factor slightly, from $44.071 to $44.058.

OIG Report Finds Medicare Could Have Saved Billions at CAHs on Swing-Bed Services

The OIG released a report on March 9, finding that Medicare could have saved $4.1 billion over a six-year period if swing-bed services at critical access hospitals (CAHs) were reimbursed using the skilled nursing facility prospective payment system rates paid to alternative facilities. In conducting its review, the OIG compared 2005-2010 Medicare claims data for swing bed services provided at CAHs with claims data for similar services provided at alternative facilities. The OIG found that swing-bed usage increased significantly from 2005 to 2010 and that Medicare spending for swing-bed services increased to, on average, almost four times the cost of similar services at alternative facilities. Based on its review the OIG concluded that ninety percent of the CAH swing-bed services could have been provided at alternative facilities at a significantly reduced rate. While CMS agreed with the OIG's finding that CAH swing-bed utilization has increased, it disagreed with its recommendation citing numerous concerns about its methodology and instead supported payment reforms which have already been proposed.

OIG Advisory Opinions

On February 13, the OIG published an advisory opinion regarding whether a provider who had been excluded from Medicare, Medicaid and other federal health care programs could receive payment for services performed prior to the exclusion date. Pursuant to a criminal plea and a False Claims Act settlement, the provider in question was excluded from participating in all federal healthcare programs for 20 years, effective October 25, 2013, and was required to divest all ownership in his or her medical practice. The provider and his or her practice submitted claims for services the provider performed prior to be excluded. Payment for these services was made after the effective date of the exclusion, and was routed to a bank account controlled by the purchaser of the medical practice. Under the proposed arrangement, the purchaser of the medical practice would transfer the payment to the excluded provider. The parties sought the OIG's opinion as to whether the proposed arrangement would violate the terms of the provider's exclusion and result in the imposition of administrative penalties.

The OIG reasoned that while an excluded individual cannot receive payment for services performed on or after the effective date of the exclusion, payment for services provided before the exclusion are not prohibited. Thus, the OIG concluded that the provider would not violate the terms of the exclusion by receiving payment. Further, the purchaser of the medical practice would be allowed to remit the payment to the excluded provider.

On March 2, the OIG released an advisory opinion in which it concluded that a proposed arrangement in which a preferred hospital network would offer deductible discounts to a Medigap plan's enrollees when they choose the network's hospitals would not result in any sanctions under the civil monetary penalties statute. Under the proposed arrangement, Medigap enrollees would receive discounts of up to 100 percent on their Medicare inpatient deductible from the hospital network. In return for selecting a network hospital and receiving the deductible discount, the Medigap plan would give beneficiaries a $100 credit toward their next premium renewal. For every discount provided by the hospital network, the Medigap plan would pay the network an administrative fee. The OIG said the proposed arrangement would be unlikely to increase utilization and would present a sufficiently low risk of fraud or abuse under the anti-kickback statute.

23andMe Gets FDA Approval to Test for Rare Disease

The Food and Drug Administration (FDA) recently announced that it granted approval for 23andMe, a DNA testing start-up, to market a direct-to-consumer genetic test for Bloom's Syndrome, a rare inherited disorder. In 2013, the FDA issued 23andMe a warning letter, demanding that the company stop marketing its Personal Genome Service. In approving 23andMe's test for Bloom Syndrome, the FDA stated that it was classifying carrier screening tests as class II and that it intends to exempt these devices from FDA premarket review. The agency will also issue a notice announcing its intent to exempt these tests and that a 30-day period will be provided for public comment. As the FDA explained, this will create "the least burdensome regulatory path for autosomal recessive carrier tests with similar uses to enter the market."

STATE DEVELOPMENTS

New Hampshire Gains Approval for Medicaid Expansion Demonstration Project

On March 4, CMS announced that it had approved, as a demonstration project, the New Hampshire Health Protection Program (NHHPP) Premium Assistance project. The premium assistance project was authorized by Senate Bill 413, which was signed into law on March 27, 2014 and established the NHHPP, but required a federal waiver to go into effect.

Under the demonstration project, the State, using Federal funding, will provide premium assistance to non-medically frail adults, aged 19-64, with incomes up to and including 133% of the federal poverty level who are neither eligible for Medicare or employer-sponsored insurance. The premium assistance will cover the cost of premiums for qualified health plans obtained through the health insurance marketplace, and eligible individuals will no longer receive coverage through the state's Medicaid program. Enrollment for existing and new beneficiaries will begin November 1, 2015, for coverage effective January 1, 2016. Although the approval would allow continuation of the demonstration project through December 31, 2018, under Senate Bill 413, the demonstration will only continue through December 31, 2016, unless the New Hampshire legislature authorizes its continuation past that point.

Beneficiaries will be able to choose between at least two silver plans. The State will pay the full cost of premiums for these plans and will provide cost-sharing reductions. Enrollees with incomes up to 100% of the federal poverty level will receive full cost-sharing reductions, such that their plans effectively have no cost sharing component. Enrollees with incomes between 100% and 133% of the federal poverty level will be given cost-sharing reductions that bring the plan to 94% actuarial value, equivalent to the cost-sharing reduction that individuals with incomes up to 150% of the federal poverty level now receive when enrolling in a marketplace plan. The State will provide eligible beneficiaries with a notice advising them of how to select a plan. There will be an auto-enrollment process in the event enrolled individuals fail to select a plan.

New Hampshire Receives Federal Grant for Home Wellness Visits

Federal Health and Human Services Secretary Burwell recently announced that New Hampshire will receive nearly $4.8 million in grant money to support home wellness visits for young children and pregnant women. The grant is part of $386 million awarded nationwide to states to support the Maternal, Infant, and Early Childhood Home Visiting Program (Home Visiting Program). Secretary Burwell says the grant will give New Hampshire the flexibility to tailor its home visit programs to address the needs of the communities they serve. The Home Visiting Program currently serves about one-third of the counties in the country with high rates of low birth weights, teen births, infant mortality and poverty.

Anthem Offers to Provide Consumers Affected by Breach with Identity Theft Protection and Credit Monitoring

Anthem Blue Cross Blue Shield now says that nearly 670,000 people, or approximately half of all New Hampshire residents, are affected by the recent data breach. Beginning February 13, current or former consumers affected by the breach were able to enroll in identity theft repair and credit monitoring services. Anthem has contracted with All Clear ID to provide services, including identity repair services, identity theft insurance, special protections for minors, phone alerts and identity theft monitoring as well as credit monitoring. The identity theft protections will apply from the day of the potential exposure of the consumers' information. Information about how to enroll is available at www.anthemfacts.com.

No Word Yet on Which Applicants Will Be Selected to Operate Medical Marijuana Alternative Treatment Centers

The nonprofit organizations which applied to operate medical marijuana alternative treatment centers are still waiting to hear if they have been selected. While it was initially believed the selections would be made within 30 days after the application deadline, state authorities are now giving no time frame for the completion of the selection process.

Reminder: Annual Reports to the Secretary of State Due by April 1, 2015

Just a reminder that corporations, limited liability companies, limited liability partnerships and certain other business entities must file annual reports with the Secretary of State by April 1 in order to avoid late filing penalties. The link to file the annual report is http://www.sos.nh.gov/corporate/annualreport/.

Legislative Update

Thursday, March 26 is crossover day for the Senate - the deadline to act on all Senate bills. Thursday, April 2 is crossover day for the House - the deadline to act on all House bills. We are monitoring the following bills:

- HB 117: This bill proposes to add physician assistants to the providers able to prescribe therapeutic cannabis. It was voted **Inexpedient to Legislate** by the House.

- HB 129: This bill mandates certain facilities and services accept donations of unused prescription drugs. Current law allows voluntary acceptance of such donations. It was voted **Inexpedient to Legislate** by the House.

- HB 151: Establishes a committee to study end-of-life decisions. It was voted **Ought to Pass** by the House with a vote of 189 for and 161 against.

- HB 164: Requires the Department of Health and Human Services to begin processing applications for registry identification cards no later than July 25, 2015. Voted **Inexpedient to Legislate** by the House.

- HB 165: Clarifies the definition of qualifying medical condition for the therapeutic use of cannabis to allow that certain diagnoses meet the definition whether or not the patient suffered the listed effects. Voted **Inexpedient to Legislate** by the House.

- HB 202: Repeals the authority of registered nurses for dispensing non-controlled prescription drugs in clinics operated by or under contract with the Department of Health and Human Services or in clinics of nonprofit family planning agencies. Voted **Inexpedient to Legislate** by the House.

- HB 271: This bill exempts from the provisions of the Controlled Drug Act a health care professional or other person who prescribes, dispenses, distributes, or stores an opioid antagonist, or who administers it to an individual suffering from an apparent opioid-related overdose. Voted **Ought to Pass with Amendment** by the House. The amendment changes the effective date of the bill from January 1, 2016 to the date of passage.

- 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 Executive Departments and Administration Committee (15-1). 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.

- 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.

- HB 337: This bill declares that if a patient admitted to a facility is not of sound mind as determined by a physician or a court, the wishes of the patient's immediate family or guardian shall take precedence over the provisions of the patients' bill of rights. Introduced and referred to House Health and Human Services Committee. Voted **Inexpedient to Legislate** by the House.

- HB 389-FN: This bill repeals the certificate of need moratorium on nursing home and rehabilitation beds. Introduced and referred to House Health and Human Services Committee. Voted **Inexpedient to Legislate** by the House.

- HB 410: This bill repeals the law prohibiting the sale of purchase of parts under the uniform anatomical gift act. Introduced and referred to Executive Departments and Administration. Voted **Inexpedient to Legislate** by the House.

- HB 413-FN: This bill establishes the governing board of polysomnographic technologists within the allied health professionals, defines the practice of polysomnography, and requires licensure of persons engaged in the practice. Voted **Inexpedient to Legislate** by the Executive Departments and Administration Committee (9-4).

- 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.

- 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.

- HB 477- FN: This bill changes the weekly compensation for temporary total disability, permanent total disability, and temporary partial and permanent partial disability. This bill also requires the Labor Commissioner to establish medical payment schedules. Introduced and referred to House Labor, Industrial and Rehabilitative Services Committee. The bill has been **Retained in Committee**.

- 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.

- 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.

- HB 548: This bill establishes the federally-facilitated health exchange as the health exchange for New Hampshire. Voted **Inexpedient to Legislate** by the House Committee on Commerce and Consumer Affairs. (11-5)

- 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.

- HB 593-FN: This bill permits qualifying patients and registered caregivers to cultivate cannabis for therapeutic use. Voted **Inexpedient to Legislate** by the House Health and Human Services Committee (9-8). With this close vote, watch for the debate on the floor of the full House.

- HB 600-FN: This bill requires employers to provide paid sick leave for employees. Voted **Inexpedient to Legislate** by House Labor, Industrial and Rehabilitative Services Committee (12-8).

- HB 628-FN: This bill declares that any facility licensed under RSA -151 may provide employment information to any other facility regarding an employee or prospective employee if the information is provided in good faith. The facility, its directors and employees will be immune from civil liability for providing the information unless the information provided is proven to be false and was provided with knowledge of its falsity. **Voted Ought to Pass with Amendment** by the House Health and Human Services Committee (17-0). The amendment changes this from a disclosure that a facility "may" make to one that it "shall" make. One word with a big difference.

- HB 670-FN: This bill prohibits discrimination against health care providers who conscientiously object to participating in any health care service. Voted **Inexpedient to Legislate** by the House (237-88).

- HB 686-FN: This bill establishes a single payer health system for New Hampshire. Voted **Inexpedient to Legislate** by the House.

- SB 7: This bill requires the joint health care reform oversight committee to provide oversight, policy direction and recommendations for legislation regarding implementation of managed care and the NH Health Protection Plan. Introduced and referred to Senate Health and Human Services Committee.

- 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.

- SB 36: This bill allows pharmacies to dispense oral contraceptives to persons 18 years of age or older without a prescription. Voted **Inexpedient to Legislate** by Senate.

- SB 45: This bill requires an injured worker and his or her health care provider to enter into an opioid treatment agreement outlining the procedures for opioid use under workers' compensation. Introduced and referred the Senate Commerce Committee.

- SB 84: This bill clarifies when it is appropriate to use telemedicine in practitioner-patient medical circumstances. Under this bill, a practitioner shall not prescribe controlled drugs, Schedule II-IV, by means of telemedicine. Voted **Ought to Pass** by Senate Health and Human Services Committee. Bill was **Laid on Table** by motion of Senator Sanborn.

- SB 108-FN: This bill make 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 Health and Human Services Committee. 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.

- SB 112: This bill requires Medicaid coverage under RSA-420-J to cover telemedicine services. Introduced and referred to Senate Health and Human Services Committee.

- SB 130: This bill establishes an opt out option for participation in the immunization registry. It is requested by the Department of Health and Human Services. Introduced and referred to Senate Health and Human Services Committee.

- 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.

- SB 176: This bill declares that primary care providers providing direct primary care pursuant to a primary care agreement are not subject to the insurance laws, provided certain conditions are met. Voted **Inexpedient to Legislate** by the Senate Commerce Committee.

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

BIOS

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