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# Healthcare Law UPDATE

July 2020

*In This Issue:*



## FEDERAL UPDATE

### Appeals Court Allows HHS Site-Neutral Payment Policy To Stand

On July 17, 2020, the U.S. Court of Appeals for the D.C. Circuit overturned a lower court ruling and upheld the Department of Health & Human Services' (HHS) "site-neutral payment policy" that reduces payments to off-campus, provider-based hospital departments. The payment policy impacts Medicare reimbursement of evaluation and management (E&M) services at all hospital off-campus settings (i.e, hospital-acquired physician practices), which had been reimbursed at higher rates compared to rates paid to independent physician offices for the same services. The new payment policy equalizes payments for these E&M services regardless of the site of service.

HHS enacted the site-neutral payment policy for its 2019 Hospital Outpatient Prospective Payment System (OPPS) as an exercise of its statutory authority to "develop a method for controlling unnecessary increases in the volume of covered services." 42 U.S.C. § 1395l(t)(2)(F). Although rate adjustments are generally required to be budget-neutral, HHS determined that the budget-neutrality requirement did not apply to methods for controlling volume.

In litigation filed by hospital organizations against HHS in 2019 for the payment cuts, the plaintiffs argued that rate cuts exceeded HHS' authority because they did not qualify as a method for controlling unnecessary increases in volume. The hospitals also argued that application of the reduced E&M payments to pre-existing off-campus departments violated the Bipartisan Budget Act of 2015, Section 603, which only authorized site-neutral payments for new off-campus departments. A federal court ruled in September 2019 that HHS had exceeded its statutory authority by making the payments site-neutral and overturned the site-neutral payment policy for E&M services contained in the 2019 OPPS. HHS appealed the court's ruling and continued the payment cuts in the 2020 OPPS.

The Court of Appeals for the D.C. Circuit overturned the lower court's ruling, holding that the Bipartisan Budget Act of 2015 does not prohibit HHS from adopting "service-specific, non-budget-neutral reimbursement cuts" as a method for controlling unnecessary increases in the volume of that service. The Court explained that the "lower the reimbursement rate for a service, the less the incentive to provide it," and, therefore, reducing the reimbursement rate is "naturally suited to addressing unnecessary increases in the overall volume of a service provided by hospitals." Accordingly, the court found that 1) the manner in which HHS made the E&M reimbursement cuts was consistent with a "reasonable interpretation" of its statutory authority to implement volume-control methods, and 2) the applicability of the payment cuts for E&M services to pre-existing off-campus sites was not a violation of the statute.

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### Abiding By the Civil Rights Act During COVID-19

In response to the public health emergency and to ensure that all people receive the care they need in the face of the COVID-19 pandemic, the Office for Civil Rights (OCR) within the U.S. Department of Health & Human Services (HHS) issued guidance on July 20, 2020 to ensure that recipients of federal aid are complying with and continue to comply with Title VI of the Civil Rights Act of 1964 (Title VI). Specifically, this guidance is aimed at informing federal aid recipients that in accepting such aid they must comply with Title VI, which sets forth that "[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance."

HHS and the OCR are dedicated to working together during this pandemic to identify and remove discriminatory barriers which bar equal access to healthcare. The OCR is responsible for ensuring compliance with Title VI and is issuing guidance to assist state and local agencies, hospital and other healthcare providers in becoming more cognizant of what they can do to ensure equal access to healthcare. For example, the guidance issued on July 20, 2020, provides that recipients of federal aid should take certain steps, including but not limited to the following:

- Appoint or select individuals to participate as members of a planning or advisory body which is an integral part of the recipient's program, without exclusions on the basis of race, color, or national origin;
- Make available to patients, beneficiaries, and customers

information on how the recipient does not discriminate on the basis of race, color, or national origin;

- Assign staff to patients without regard to race, color, or national origin and do not honor a patients' request for a same-race healthcare provider; and
- Not assign rooms according to race, color, or national origin.

While the OCR is working to ensure compliance, HHS is working diligently to identify populations that are more vulnerable to COVID-19 and taking steps to improve testing, treatment, and prevention. The Minority Health Office of HHS has agreed to build in cooperation with The Morehouse School of Medicine the "National Infrastructure for Mitigating the Impact of COVID-19 within Racial and Ethnic Minority Communities Initiative." This partnership will utilize a diverse network of groups, including state, territorial, tribal, and community and faith-based organizations to provide culturally and linguistically diverse COVID-19 information in order to help those hit hardest by COVID-19.

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## Protecting Access to Post-Covid-19 Telehealth Act of 2020 Introduced

On June 29, 2020, 340 organizations, including the American Telemedicine Association, wrote a letter to Congress requesting permanent telehealth reform that will remove telehealth restrictions once the national health emergency ends. In response to the letter, Congress wrote a letter to HHS and CMS asking for a written timeline regarding future plans for telehealth reform including a request for a list of permanent telehealth changes to Medicare, Medicaid, and CHIP rules that require Congressional action. The members of the Congressional Telehealth Caucus recently proposed the Protecting Access to Post-COVID-19 Telehealth Act of 2020, which addresses many of the requests outlined in the June 29, 2020 letter sent to Congress including, eliminating geographic and originating site restrictions, establishing the patient's home as a permissible originating site, and making HHS' disaster waiver authority permanent for future emergencies.

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## Additional COVID-19 News

Over the past several months, news in the healthcare sector (and, in fact, almost all sectors) has been overwhelmingly COVID-oriented. In our May *Healthcare Law Update*, we summarized a number of federal highlights and have continued to provide you with information in the form of alerts and webinars. Below are a few federal-level highlights over the past couple of months. Please visit our COVID-19 Resource Center for more information on these and other COVID-19 topics.

***HHS Issues Guidance on Eligible Expenses and Lost Revenues to be Reimbursed with Provider Relief Funds*** – On June 3, 2020, HHS announced what expenses and lost revenue would be considered for reimbursement with Provider Relief Funds on June 3, 2020. *According to the Terms and Conditions, the recipient must certify that the payment will only be used to prevent, prepare for, and respond to coronavirus*, and that the Payment shall reimburse the recipient only for healthcare-related expenses or lost revenues that are attributable to coronavirus. The HHS clarified the eligible expenses and lost revenues. Click here for our full article on this topic.

***HHS Launches New Distribution and Payment Portal for Medicaid and CHIP Providers*** – The Department of Health & Human Services (HHS) is accepting applicants for distributing $15 billion as a Targeted Distribution through August 3, 2020. The deadline was extended from the prior deadline of July 20, 2020. This Targeted Distribution is open to eligible Medicaid and Children's Health Insurance Program (CHIP) providers. To be eligible to apply for this Medicaid/CHIP payment, the applicant must meet certain specific requirements. Payments will be made on a rolling basis, provided that HHS has validated the provider's status with the HHS. Payments will be approximately 2% of reported gross revenue from patient care for the calendar year 2017, 2018, or 2019, depending on the year selected by the applicant. Only those in good standing with the HHS will be eligible for these payments. Click here for more details about this issue.

***Provider Relief Fund Payments are Taxable Income, Says HHS and IRS*** – Grant payments received from the Provider Relief Fund program by for-profit providers will be treated as taxable income, according to the Department of Health & Human Services (HHS) and the Internal Revenue Service (IRS). Tax-exempt providers will be exempt from paying taxes on these payments unless the payment is used to reimburse expenses or lost revenue attributed to unrelated trade or business of the tax-exempt provider. If Congress intends for these payments to be non-taxable, further action will be necessary. Our latest guidance on this regulation can be found here.

***HHS Launches New Provider Relief Distribution to Dentists*** – Provider Relief Funds now may be distributed to dentists, who were previously ineligible to receive such funds. The deadline to submit applications for these Provider Relief Funds is August 3, 2020. The payments will be available to dentists who do not bill Medicare or Medicaid. Dentists, however, will not be eligible to receive these funds if such dental providers previously received or rejected and returned a prior Medicare-focused distribution or the Medicaid/CHIP-focused distribution. Certain other eligibility requirements must be met as well. Applicants will need to submit tax documentation through the online portal. Payments will be made based on 2% of the reported revenue from patient care, based on the most recent reported tax filing. For more information about this matter, click here.

Please visit our COVID-19 Resource Center for additional information, including our on-demand webinar series.

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# STATE UPDATE

## New Jersey Legislative Update

***Bill Introduced to Restrict the Use of Restrictive Covenants*** – On May 4, 2020, Bill A4003 was introduced in the New Jersey Assembly to restrict the use of restrictive covenants in physician employment contracts. An identical bill was introduced in the New Jersey Senate on May 7, 2020. The Bill provides that, with limited exceptions, covenants in a contract or agreement that creates or establishes the terms of a partnership, employment, or other form of professional relationship that restrict the ability of a physician to practice in a geographic area for any period of time after termination of the partnership, employment, or professional relationship, will be deemed void and unenforceable. Exceptions to the foregoing prohibition include the following: (1) a restrictive covenant that prohibits a physician from leaving a hospital system or a group practice comprising 30 or more physicians to join any other hospital system or group practice comprising 30 or more physicians within a given geographic area; and (2) a restrictive covenant that prohibits a physician from leaving a hospital system or a group practice comprising 30 or fewer physicians to join any other hospital system or group practice comprising 30 or fewer physicians within a given geographic area.

***New Rule Permits Advanced Practice Nurses to Dispense Maintenance and Detoxification Drugs*** – Under new rules adopted by the Board of Nursing effective July 6, 2020, an advanced practice nurse may dispense narcotic drugs for maintenance or detoxification treatment if the advanced practice nurse has met the training requirements of, and is registered pursuant to, certain Federal Drug Abuse Prevention and Control laws (21 U.S.C. 823(g)). If an advanced practice nurse is qualified to dispense narcotic drugs for maintenance or detoxification treatment, he or she may dispense such drugs even if his or her collaborating physician has not met the requirements of such Federal laws, as long as the joint protocol between the advanced practice nurse and the collaborating physician includes the physician's written approval for the dispensing of such drugs. Under the new rules, an advanced practice nurse may also prescribe services for treatment of substance-use disorder, pursuant to the joint protocol between the advanced practice nurse and his or her collaborating physician.

***Bill Introduced to Permit Healthcare Providers and Insureds to File Covid-19-Related Claims Within One Year of Date of Service*** – On June 15, 2020, Bill A4261 was introduced in the New Jersey Assembly to permit healthcare providers and insureds to file certain COVID-19-related health insurance claims within 365 days of the date of service. An identical bill was introduced in the New Jersey Senate on June 29, 2020. Under the Bill, healthcare professionals, healthcare facilities and insureds may file claims for treatment provided between January 27, 2020 and the end of the Public Health Emergency and State of Emergency declared by Governor Phil Murphy in Executive Order 103, March 9, 2020, within 365 days of the last date of service for healthcare services provided during the covered period.

***BME Proposes to Permit Midwives to Administer Nitrous Oxide*** – On July 20, 2020, the New Jersey Board of Medical Examiners (the Board) proposed to amend the rules governing licensed midwives to permit them to administer or facilitate the administration of nitrous oxide for pain relief during the intrapartum and postpartum stages when they are providing services in a healthcare facility licensed by the Department of Health. The Board had received a request from a healthcare facility to permit licensed midwives to administer nitrous oxide as labor analgesia. Upon reviewing the request, the Board determined that the administration of nitrous oxide is within the training and scope of a licensed midwife, and that it is, therefore, appropriate for midwives to administer nitrous oxide for pain relief both during labor and after delivery, so long as they do so only in healthcare facilities licensed by the Department of Health. Comments on the proposed amendment are due by September 18, 2020.

***New Continuing Education Rules for Ophthalmic Dispensers*** – On July 20, 2020, new rules became effective regarding continuing education requirements for ophthalmic dispensers. Of the twelve credits of continuing education that ophthalmic dispensers must complete every biennial period, at least three credits must be in dispensing of contact lenses, at least two credits must be in statutes and rules governing the practice of ophthalmic dispensing and at least five credits must be in topics relevant to the practice of ophthalmic dispensing. No more than two credits may be in topics related to management, sales, or marketing. In addition, newly licensed ophthalmic dispensers must complete one credit in blood-borne pathogens and, during the 2021-2022 biennial renewal period, currently licensed ophthalmic dispensers must also complete one credit in blood-borne pathogens.

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## Brach Eichler In The News

Managing Member and Healthcare Law Chair **John D. Fanburg** is quoted extensively in *ROI-NJ* on June 26 about the challenges ASCs are facing due to COVID-19-related requirements.

Member **Lani M. Dornfeld, CHPC**, comments to *Bloomberg Law* about the issues posed by telehealth consent mandates on June 15.

**John Fanburg** spoke to *Becker's Healthcare* on July 7 about the difficulties ASCs are having complying with COVID-19 testing rules.

In the July 14 edition of the *New Jersey Law Journal*, **John Fanburg** shares his perspective on the reopening of law firm offices .

## HIPAA CORNER

***More than $1 Million Settlement for Stolen Unencrypted Laptop*** – On July 27, 2020, the Department of Health & Human Services (HHS) announced a settlement with Lifespan Health System in the amount of $1,040,000 relating to the theft of an unencrypted laptop that contained protected health information (PHI). The breach affected more than 20,000 individuals. Critical to the harsh penalty was the determination by the HHS Office for Civil Rights that Lifespan had engaged in systemic non-compliance with HIPAA, including a failure to encrypt the electronic PHI held on the laptop, the lack of device and media controls (e.g., controls over the inventory and movement of devices, including within and outside of the organization), and the failure to have in place a business associate agreement. In addition to the monetary settlement, Lifespan agreed to a corrective action plan that includes two years of monitoring.

***SAMHSA Issues Final Rule Amending 42 CFR Part 2, Federal Confidentiality Rules for Substance-Use Disorder Treatment Facilities*** – On July 15, 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued a final rule amending the federal "42 CFR Part 2" regulations (Part 2 Rules) governing the confidentiality of substance-use disorder (SUD) treatment facility records. The Part 2 Rules were initially promulgated in 1975 to address the need to maintain in strict confidence records relating to SUD treatment. The rules were amended in 1987, 1995, 2017, and 2018, and are being further amended in light of the opioid crisis and changes required under the CARES Act in response to the COVID-19 epidemic. The Part 2 Rules will be further amended next year, as required under the CARES Act, to better align the Part 2 Rules with HIPAA.

The amended Part 2 Rules do not alter the basic confidentiality framework prohibiting the use of SUD patient records in criminal prosecutions against SUD patients, absent a court order and restricting the disclosure of SUD treatment records without written consent except in very limited circumstances, such as a bona fide medical emergency, for scientific research, audit, or program evaluation or based on a court order obtained after following specific procedures.

Some highlights of the amendments include:

- Treatment records created by non-Part 2 providers based on their own patient encounter(s) are not covered by the Part 2 Rules, unless any SUD treatment records previously received from a Part 2 program are incorporated into such records. Segmentation or holding a part of any Part 2 patient record previously received can be used to ensure that new records created by non-Part 2 providers will not become subject to Part 2.
- When an SUD patient sends an incidental message to the personal device of an employee of a Part 2 program, the employee will be able to fulfill the Part 2 requirement for "sanitizing" the device by deleting that message.
- A SUD patient may consent to disclosure of the patient's Part 2 treatment records to certain entities (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure.
- Disclosures for the purpose of "payment and healthcare operations" are permitted with written consent, in connection with an illustrative list of 18 activities that constitute payment and healthcare operations now included under the Part 2 Rules.

*If you would like assistance with your HIPAA or 42 CFR Part 2 privacy and security program, in managing or reporting a breach incident, or in business associate analysis and contracting, contact:*

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