

Newsletter

Spring Issue | March 17, 2021

MESSAGE FROM THE CHAIR



Jeff Cook
Forrest Health,
General Counsel

Last week we remembered the one year anniversary of the first COVID-19 case in Mississippi. President Trump declared a National Emergency on March 13, 2020, and Governor Reeves declared a State of Emergency a day later on March 14. Back then, those daily reports from the Mississippi Department of Health confirmed the need for the emergency declarations and it was clear the disease was spreading among Mississippians faster than we could have imagined. It was a fight against a disease that the world, and Mississippi, did not see coming. We lost loved ones and colleagues to the disease. We lost our normal lives too. One year later, I am grateful for our health and excited that spring is upon us with multiple vaccinations for COVID-19 and hope for normalcy.

During the last year, we health lawyers have seen a lot of change too. The pandemic forced us to change the way health care was delivered and so rules and regulations were updated. We opened up telemedicine services, testing clinics, and all raced to find personal protective equipment (PPE). Early on, we could not read as fast as CMS was issuing those Section 1135 waivers. We had to advise on the HHS CARES Act Provider Relief Fund, FEMA eligibility, and Paycheck Protection Program loans. We also had the unimaginable tasks of organizing resource allocation emergency plans with our physicians and hospital administrators while praying we would never have to use any of them. Add to that, there were changes to the Stark Law, preparation for the 21st Century Cures Act Final Rule on information blocking and navigating value-based payer models with our clients. We are coming out of the other side this pandemic changed, and I'd argue that health care in our state will be better for it.

In this newsletter you will find great articles written by our Health Law Committee Members. Jonathan Will has penned a piece on the new Biden Administration's agenda and where we may be headed. Also, Stan Ingram has provided an update on telemedicine. Lastly, Lane Staines has provided a Mississippi Legislative update from the ongoing session.

Looking forward, the Health Law Section will present a virtual 4-hour CLE on April 9 titled "Health Care Law Update: Keeping Stride with Legal and Regulatory Changes." We have some great Mississippi health lawyers that will present on relevant topics. See the list of confirmed presenters on the next page.



Health Care Law Update:

Keeping Stride with Legal and Regulatory Changes

April 9, 2021 | 8:00am - 12:00pm

<i>8:00 - 8:45am</i>	Medicare Fraud and Abuse Update Jonell Beeler (Baker, Donelson, Bearman, Caldwell & Berkowitz, PC)
<i>8:45 - 9:30am</i>	Certificate of Need Program Update Christin Williams (Director of the Officer of Health Policy and Planning, Mississippi State Department of Health) and Barry Cockrell (Baker, Donelson, Bearman, Caldwell & Berkowitz, PC)
<i>9:30 - 10:15am</i>	Mississippi Legislative Update Richard Roberson (General Counsel, Mississippi Hospital Association)
<i>10:15 - 11:00am</i>	Employment Law Update Nakimuli Davis-Primer (Baker, Donelson, Bearman, Caldwell & Berkowitz, PC)
<i>11:00am - Noon</i>	Ethics Hour Adam Kilgore (General Counsel, The Mississippi Bar)

TELEMEDICINE UPDATE



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More than any other event of recent times, the Coronavirus Disease 2019 (COVID-19) pandemic has awakened the healthcare system and patients nationwide to the use of telemedicine. Mississippi and the nation currently remain under the Public Health Emergency (PHE) for COVID-19 as declared by the Secretary of Health and Human Services (HHS) under Section 319 of the Public Health Service Act (42 U.S.C. Section 247d). In a recent communiqué to state governors, the Secretary of HHS stated that the current PHE was renewed effective January 21, 2021, and will be in effect for ninety (90) days. Further, HHS has determined that the PHE will likely remain in place for the entirety of 2021, and when a decision is made whether to terminate the declaration or let it expire, HHS has agreed to provide states with a 60-day notice prior to termination. In similar fashion, on December

22, 2020, the Centers for Medicare & Medicaid Services (CMS) released a state health official letter outlining how the states are expected to unwind emergency authorities and resume normal eligibility, but again advising that the PHE will likely remain in place throughout 2021.

Not unexpectedly, the medical industry's reaction to the PHE has served to solidify telemedicine as an integral part of health care. In response to a March 14, 2020 Emergency Declaration by Governor Tate Reeves, the Mississippi State Board of Medical Licensure issued a series of proclamations permitting out-of-state physicians to provide telemedicine services to Mississippi citizens without the necessity of securing permanent licensure. The only requirement was the establishment of an existing doctor-patient relationship, and even this was waived for certain specialties (pulmonologists, nephrologists, etc.) as determined by State Health Officer Thomas Dobbs, M.D. As a result, the Medical Board experienced a tremendous increase in the number of out-of-state physicians providing telemedicine. On October 26, 2020, with authorization from the State Health officer, the Medical Board terminated the previous proclamations, thus requiring the out-of-state physicians who wish to continue providing telemedicine to Mississippi patients to submit and go through the normal application process. Many have done so. The net effect was a substantial increase in the number of physicians providing telemedicine, both in-state and out-of-state.

The growth of telemedicine has been fueled to some extent by the actions taken by state and federal agencies to address the PHE. Some of the most notable changes to telemedicine on the federal level brought about by federal legislation and policy changes, including the Coronavirus Aid, Relief, and Economic Security (CARES) Act, are [continued on next page]:

1. Medicare pays physicians for telehealth services (both audio-video and audio-only) at the same rate as in-office visits.
2. Physicians can provide telehealth services to all patients, not just those in rural areas. Prior to this waiver, Medicare could only pay for telehealth on a limited basis, that is, when the person receiving the service was in a designated rural area.
3. Telehealth rules were relaxed so physicians could provide audio-only evaluations to both new and established patients.
4. CMS temporarily suspended physician supervision requirements for Certified Registered Nurse Anesthetists (CRNAs), subject to state law.
5. Expanded access to telehealth, virtual check-ins, e-visits, and telephone calls for practitioners such as licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, speech-language pathologists.
6. DEA allows physicians to prescribe controlled substances based on telehealth visits (subject to state laws). Further, DEA has relaxed the requirements for the issuance of oral prescriptions for schedule II controlled substances.
7. HHS Office of Civil Rights (the agency responsible for enforcing HIPAA) relaxed its rules so that physicians could use common audio-video programs – such as FaceTime, Skype, and Zoom – to provide telehealth services and will not impose penalties for good faith noncompliance with the relaxed HIPAA rules regarding telehealth.
8. List of covered telehealth services were expanded to include:
 - Emergency visits
 - Initial nursing facility and discharge visits
 - Home visits
 - Therapy services
9. CARES Act extends telehealth coverage to Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs).
10. CARES Act eliminates the requirement that nephrologists conduct required periodic home visits for dialysis patients in person.
11. CARES Act allows qualified providers to use telehealth to fulfill hospice recertification requirements for face-to-face visits.
12. CARES Act allows a veteran's enrollment or re-enrollment in a Veteran Directed Care Program to be conducted via telehealth.

We note that the above is only a small list of the telehealth waivers and relaxations and as we progress through the PHE, other changes are sure to come. As one commentator has noted, the recent insurgence of telemedicine has reached Washington. The title of a recent article in mHealthIntelligence says it all: “Washington is Awash in New and Reintroduced Telehealth Bills.” At least three (3) additional bills had been filed over the past two weeks (as of January 29, 2021) seeking to expand connected health access and coverage either during or beyond the coronavirus pandemic. Therefore, as we gradually close the emergency status of the coronavirus pandemic, and the smoke begins to clear, it will be interesting to observe the metamorphosis of telemedicine.

Biden's Health Care Agenda: What is on the Horizon?



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While the health care system in the United States never seems to be particularly stable, its dynamic nature is exacerbated by political transition.

As President Joe Biden settles into his new administration, his health care policy agenda will come into sharper focus. The following explores where we seem to be heading in the contexts of the (1) Affordable Care Act (ACA), (2) COVID-19 Pandemic, and (3) Stark and Anti-kickback final rules that have been languishing for quite some time.

Affordable Care Act

Biden has balked at the idea of moving toward a single-payer system along the lines of Bernie Sanders' "Medicare for All" proposal. That said, he has made clear that he intends to shore up the ACA as opposed to pursuing

efforts to dismantle it (as former President Trump attempted). The pillars of Biden's health care roadmap include adding a Medicare-like public option to the health care exchanges, offering financial incentives to states to expand Medicaid that have not (especially Texas, Florida, and Georgia), expanding ACA subsidies for lower-income Americans regardless of Medicaid expansion, introducing "Medicare for More" legislation (discussed below), and pushing a greater focus on overall public health concerns. Biden, like Trump before him, also seems legitimately interested in reducing drug costs by repealing existing laws that prohibit Medicare from negotiating lower prices with drug manufacturers.

One of the first things Biden did upon becoming President was to sign an executive order on January 28 that re-opened enrollment in the ACA exchanges. Trump had limited enrollment periods and cut funding for advertising open enrollment periods. Biden has also expressed interest in reinstituting the individual mandate penalty, which could potentially be effected by an executive order. Other initiatives, like Medicare for More, the public option, and capping out-of-pocket expenditures for health insurance at 8.5% of income (down from nearly 10% under the ACA) would require legislation, and thus, political cooperation. Biden is also exploring waiver provisions that would give states flexibility to provide expanded insurance coverage to their citizens, including state-level, single-payer experiments.

In concept, Medicare for More would reduce Medicare eligibility from 65 to 60. The goal would be to add younger, healthier individuals to the Medicare risk pool in order to spread the risk and reduce the per capita cost of the program. And because those same 60 year-olds tend to incur more health care expenditures than younger individuals, Medicare for More would also serve to benefit private insurance risk pools. In other words, with 60-year olds participating in Medicare, private insurance risk pools would have a lower-cost population which, in turn, could reduce premiums for the younger, healthier individuals receiving insurance through the open market. That is the theory anyway. Instead, for profit, private insurance may well seek to retain any savings realized by implementation of Medicare for More as opposed to passing those savings on to enrollees.

Due to the prohibitive expense of medical services, access to health care in the United States goes hand in hand with insurance. In 2010, 50 million Americans were without health insurance. By 2016 that number was reduced to 20 million, but had shot back up to 30 million by the end of 2020 (around 11% of the population). Biden's goal is clearly to expand access during his administration, and he is now offering 95% federal funding for Medicaid expansion. For instance, 4 million individuals would gain insurance if the dozen holdout states expanded Medicaid. Nearly one-third of those individuals live in Texas, a state in which 18% (nearly twice the US percentage) is uninsured. These numbers have worsened due to the COVID-19 Pandemic, and individuals without insurance who were hospitalized due to COVID are recovering from illness only to find themselves in insurmountable medical debt.

Pandemic Response and Focus on Public Health

Biden's recent public address marking the one-year anniversary of the Pandemic included aggressive goals and a more active role for the federal government in the nation's Pandemic response. The early rollout of vaccinations has been plagued by inconsistent information and difficulty in scheduling and administering vaccines. Nonetheless, Biden suggested that all states should open vaccinations to all adults by May 1. In addition, Biden committed to launching a federally supported website and call centers to facilitate vaccine distribution as well as deploying military personnel to assist with vaccinations. The rollout is complicated by the fact that, although the federal government procures and distributes vaccines to the states, it is the states (and other non-federal jurisdictions) that control eligibility and vaccination itself.

The Biden administration stands behind the CDC's guidance that mask wearing will still be a vital preventative strategy (even after widespread vaccination) in terms of reopening schools and businesses. Beyond this, the administration has emphasized the role of social determinants of health and the impact of economic factors on not just COVID-related health concerns, but overall health statistics. Such social determinants include nutrition, education, housing, and social support networks. These concepts are consistent with the ACA's overall movement toward integrated care and patient-centered medical homes. Of course, integrated and coordinated care through accountable care organizations also calls to mind potential hindrances to those efforts historically found in the Stark and Anti-kickback statutes that led to revising the rules associated with those laws.

Revisions to Stark/Anti-kickback Laws

Changes to modernize the Stark and Anti-kickback statutes have been long-awaited and enjoy bipartisan support. Broadly speaking, the changes serve to provide greater flexibility for providers to engage in value-based care and to clarify and ease certain restrictions on physician compensation arrangements with hospitals as integration takes place. Implementation of the final rules was set to occur on January 19, 2021; however, the Biden administration issued a memo the next day requesting agencies to postpone implementation to allow the new administration to review the rules.

Some have suggested that the final rules may be at risk of further delay (or modification) because of a technical failure to comply with the 60-day notice and comment period. That said, when contacted in mid-February by a health care consulting agency, the Centers for Medicare & Medicaid Services (CMS) apparently issued a statement indicating that the final Stark rules (regarding physician self-referrals) are considered by CMS to be effective. A similar statement has not been released from the Office of Inspector General (OIG) regarding the Anti-kickback statute final rules, but given the collaboration between CMS and OIG, and the bipartisan support associated with these final rules, it is unlikely that they would be treated differently. Even still, as we await confirmation of the final members of Biden's cabinet, it is possible that further revisions could be made to the final(?) rules. This is an area that we will have to continually monitor . . . at least in the near future.

Sources:

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<https://www.bvresources.com/articles/bvwire/is-the-new-cms-rule-that-impacts-healthcare-valuations-now-at-risk>

2021 LEGISLATIVE SUMMARY OF HEALTHCARE BILLS



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Though the Mississippi Legislature remains in session, the Health Law Committee is pleased to provide you with this summary of healthcare-related bills currently before the Mississippi Legislature as of press time:

House Bill 72: This bill would amend Miss. Code § 73-25-38 to provide immunity to dentists for providing charitable health services, or services without charge, in the circumstances outlined in the statute.

House Bill 95: This bill revises Miss. Code § 73-17-11, to authorize the State Board of Nursing Home Administrators to conduct a criminal history records check on any applicants for licensure. The revision would also provide for applicants to be fingerprinted, with results disseminated to the Board for a suitability determination. Applicants would not be responsible for the cost of requesting and obtaining state and national criminal history records. The bill also exempts any licensed administrator who is a member of the Legislature

and serves on the Public Health and/or Medicaid Committee from continuing education requirements. The bill would extend the date of the previous repealer.

House Bill 200: This bill proposes to abolish the requirement that, in order to qualify for remote patient monitoring services, patients must have had a “history of costly service use” due to chronic conditions (as evidenced by 2 or more hospitalizations within the most recent 12 months). The bill makes prior authorizations optional.

House Bill 208: House Bill 208 would re-enact Miss. Code § 73-31-31, et seq. pertaining to licensure of psychologists. It would also amend Miss. Code § 73-31-13 to revise the requirements on supervised internships. The repealer date would be extended to July 1, 2025.

House Bill 294: This bill would abolish the repealer in Miss. Code § 41-29-137.1 in order to allow medical directors of hospices to continue to prescribe controlled substances for hospice patients with terminal disease pain without the need for a face-to-face patient encounter.

House Bill 493: This bill would allow for counties and municipalities to offer a county or municipal employee, who is Medicare eligible, specific benefits, such as supplemental compensation, if the employee chooses to obtain Medicare coverage rather than participate in the county medical program.

House Bill 1174: House Bill 1174 would authorize the Department of Corrections to provide for and arrange hospice services for inmates who are terminally ill. If the Department of Corrections is providing the hospice services, no hospice license would be required.

House Bill 1205: This bill would revise the definition of “telemedicine” to include “HIPAA-complaint telecommunications systems.”

House Bill 1302: This bill would amend Miss. Code § 73-19-1 to permit optometrists to treat specified diseases and conditions of the eye and eyelid by prescribing certain pharmaceuticals, perform primary eye care procedures as determined by the Board of Optometry, performing and ordering lab tests for diagnosis purposes, use local anesthetic to treat eyelid lesions (after obtaining certification), and use local anesthesia by injection to perform other specified procedures. Optometrists cannot perform cataract surgery or other surgical procedures requiring general anesthesia, but if credentialed, can perform laser capsulotomies. The State Board of Optometry would create a 3-year pilot program for up to twenty optometrists to perform ophthalmic laser capsulotomies. Finally, the bill would expand Miss. Code § 73-19-157 to allow optometrists to use and prescribe any pharmaceutical medications that are rational and appropriate for a patient’s examination, diagnosis, management of visual defects, or abnormal eye conditions or diseases as authorized within the statute and excluding certain controlled substances. Optometrists would be permitted to give inoculations in a public health emergency when authorized by the State Health Officer.

Senate Bill 2021: This bill proposes to house the Coordinator of Mental Health Accessibility within the Department of Finance and Administration, rather than the State Department of Mental Health, as it is currently under Miss. Code § 41-20-3. The bill replaces other references to the State Department of Mental Health with the Department of Finance and Administration. Additionally, the Public Procurement Review Board would not be responsible for promulgating rules and regulations pertaining to related personal service contracts under this statute.

Senate Bill 2631: This bill would ensure that providers are reimbursed for telemedicine services using appropriate medical codes and that negotiations pertaining to reimbursement for these services be conducted in the same manner as negotiations for reimbursement for in-person services. The bill also prohibits health insurance and employee benefit plans from limiting coverage to provider-to-provider consultations only. Finally, the bill expands the definition of “telemedicine” under the act.

Senate Bill 2746: This bill would enact “Hudson’s Law,” which requires health care providers who provide prenatal, postnatal, or genetic counseling services to provide educational material from the State Department of Health to new or expectant parents who receive a positive test for Down Syndrome.

Senate Bill 2750: This bill would amend Miss. Code § 73-21-73 to remove the requirement that a pharmacist to whom a practitioner delegates the authority to conduct certain prescribing functions must perform these functions within an institutional setting or with individual patients. It also proposes to remove the requirement that a “specific protocol agreement” be signed and filed on each patient.

Senate Bill 2799: This bill proposes to make numerous technical amendments and revisions to Medicaid services provisions in Miss. Code § 43-13-117. It would also remove the moratorium on mental health beds and restrictions on post-acute residential brain injury rehabilitation facilities and remote telemonitoring services as found in Miss. Code §§ 41-7-191, 41-75-5, and 83-9-353, respectively.