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Louisiana Hospital Association

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Notices:

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Articles:

Louisiana AG Addresses COVID-19 Drug Treatment and Provider Statutory Protections

By Adam Thames

Given the unprecedented COVID-19 health crisis and surge of patients treated by healthcare providers, Louisiana Attorney General Jeff Landry has issued a memorandum addressing healthcare providers' concerns regarding the prescription of Hydroxychloroquine and Zithromax to COVID-19 patients. The AG's memorandum also analyzes how Louisiana liability laws stack up in comparison to the New York laws that have garnered so much media attention during the last few weeks. The following is a short summary of the information contained in the AG's memorandum.

Hydroxychlroroquine and Zithromax have been pushed aggressively by certain sectors of the government to combat the virus pending a vaccine, and the use of these drugs is a hot topic of conversation in the media. Many doctors, however, remain skeptical of its efficacy in treating COVID-19 and are concerned with unintended side effects. Presumably to help put healthcare providers at ease, the Attorney General's memorandum states that any doctor who prescribes these drugs to patients in Louisiana in connection with the COVID-19 epidemic and pursuant to the Food and Drug Administration (FDA) approval guidelines should fall within the immunity statutes in Louisiana protecting healthcare providers from liability, absent "gross negligence." The Attorney General does limit his opinion, to some extent, by stating that the facts and circumstances of each case must still be considered and makes it clear that immunity under Louisiana law does not necessarily protect a provider from federal law claims concerning the use of these medications.

As to any potential federal law claims that would not be immune under Louisiana law, it is important to note that the U.S. Department of Health and Human Services (HHS) has already issued a Declaration to limit liability for companies and providers engaged in medical countermeasures against this pandemic. Specifically, the Declaration provides "…liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving 'willful misconduct' as defined in the Public Readiness and Emergency Preparedness Act." Licensed physicians are included within the definition of "Covered Persons" and under the HHS Declaration, licensed physicians sued for negligence for allegedly

prescribing the wrong dose of a drug to combat COVID-19 is a specific example of an action entitled to immunity. Thus, the HHS Declaration and the Public Readiness and Emergency Preparedness Act may, under certain circumstances, offer protection to Louisiana healthcare providers on the front lines who are later sued for negligence under federal law.

The AG's memorandum also analyzed the difference between Louisiana and New York law on healthcare liability during a public health emergency. Louisiana Health Emergency Powers Act (LHEPA) provides that, during a state of public health emergency "**any health care providers** shall not be found civilly liable for causing the **death of, or, injury to, any person or damage to any property** except in the event of **gross negligence** or **willful misconduct**." By comparison, New York's Governor Cuomo recently issued an Executive Order for a temporary suspension an modification of existing healthcare liability law that states in pertinent part: "**all physicians, physician assistants, specialist assistants, nurse practitioners, registered nurses, and practical nurses** shall be immune from civil liability for any **injury or death** sustained directly as a result of an act or omission by such medical professional in the course of providing medical services in response to the COVID-19 outbreak, unless it is established that such injury or death was caused by **gross negligence**."

The Attorney General's memorandum makes a strong case for why Louisiana law is actually more favorable for our healthcare providers than those recently put into effect in New York. While both state laws provide the heightened "gross negligence" standard, the Attorney General's memorandum makes it clear that Louisiana law protects all healthcare providers as opposed to only the six categories of healthcare providers listed in New York's law. Secondly, and perhaps the most important distinction between the two states, the AG's memorandum points out that New York's law is only triggered by or related to a provider's treatment in response to COVID-19 whereas Louisiana's law is written more broadly to protect all providers performing any kind of medical treatment during the duration of the public health emergency. Third, the AG's memorandum points out that Louisiana law extends to injury, death and property damage whereas New York's law only extends to injury or death. Lastly, the Attorney General's memorandum states that any attempt to alter the current immunity statutes, either through statute or executive order, during the public emergency will likely be declared unconstitutional.

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CARES Act Relief: Conditions, Compliance, and Potential Whistleblower Complaints
By Catherine M. Maraist

The CARES Act (Coronavirus Aid, Relief, and Economic Security Act), the Coronavirus Preparedness and Response Supplemental Appropriations Act, and the Families First Coronavirus Response Act all provide funds to healthcare providers. In applying for funds under these Acts, HHS has set up "Relief Fund Payment Terms and Conditions." As with any government grant program, compliance with the terms and conditions form the basis of the government's eventual evaluation of any complaint it may receive or any audit it may conduct regarding the healthcare provider's use of the grant funds.

The Terms and Conditions

The terms and conditions for relief fund payment include both conditions specific to the emergency funds and those more general conditions generally associated with government grants. **The "terms and conditions" are deemed "accepted" if the healthcare provider retains the payment for 30 days without contacting HHS regarding remittance of the funds**. The HHS gives such a provider a 30-day period that the amount it received is more than it needs for allowable reimbursable costs without being bound by the terms and conditions.

The specific terms include the following:

- The healthcare provider must be a Medicare provider and not excluded from participation; it must have billed Medicare in 2019; and it must have provided "diagnoses, testing, or care" for individuals with possible or actual cases of COVID.

- The healthcare provider must use the funds only to "prevent, prepare for, and respond to coronavirus," and the funds shall be used only for healthcare-related expenses or lost revenues that are attributable to coronavirus.
- The healthcare provider cannot use the funds to reimburse for expenses or losses that other sources are obligated to reimburse.
- For those that receive more than $150,000 in funds, a quarterly report must be submitted to the Secretary of HHS and the Pandemic Response Accountability Committee within ten days of the ending of each quarter.
- The healthcare provider shall maintain sufficient records and documentation to substantiate the costs incurred.
- The healthcare provider cannot collect from a patient tested or treated for COVID-19 any out-of-pocket expenses greater than what the patient would have otherwise been required to pay if the care had been provided in-network.

The more general terms include many standard provisions that are likely not a concern of healthcare providers, but notable terms include:

- None of the funds can be used to pay salaries in a rate in excess of Executive Level II.
- None of the funds may be made to an entity that requires employees or contractors to sign confidentiality agreements that prohibit or restrict them from reporting fraud, waste, or abuse.
- The funds cannot be used to satisfy an unpaid federal tax liability.
- The funds cannot be given to any corporation convicted of criminal liability.

HHS encourages the reporting of fraud, waste, and abuse in the relief money granted. Grant money is often abused, because the conditions are often broad, as they are here. This is even truer in emergency cases, as the government's response is aimed at casting a wide net of relief. In such cases, the government relies heavily on whistleblowers to police the improper use of funds. Here is a bare bones, non-exclusive list of the sort of things we will likely see reported by whistleblowers:

- **Low-hanging fruit:** These are the actual fraudulent claims—i.e., a healthcare provider who treats few or no COVID-19 patients who receives funds that will more than cover the losses. These will go straight to criminal investigation. As for the automatic distributions, providers who believe that HHS did not have adequate cost report data on file for their distribution are allowed to submit revenue information to receive additional general distribution funds. Such a process could lead to outright fraudulent representations by unscrupulous providers.
- **Retention of funds:** A provider accepts the funds in good faith but does not experience the financial loss to justify the award of funds. It is hard to give back free money, so the provider may inflate losses and/or other documentation in its reports.
- **Hidden salaries/profit:** This is creative accounting at its best. While not "low hanging fruit" because of the complexity of the accounting involved, this could end up on the criminal side if the loss to the government is egregious enough, or the misrepresentation is knowing/intentional.
- **Covering existing losses/debts:** The funds can only be used to cover "losses attributable to coronavirus." Any amount used to pay a past debt would likely be highly suspect. The more creative the accounting, the more suspect it will be.
- **Stretching the definition of "attributable losses:"** Granted, although the parameters are not well defined, the government will likely be satisfied with a plausible and well-documented attribution of loss.
- **Stretching the definition of "treatment of coronavirus:"** This will also likely be given broad interpretation, but some may become creative. For example, merely mentioning "coronavirus preventative measures" where the encounter was not motivated by testing, diagnoses, or treatment may be suspect.
- **Out-of-pocket limitation violation:** Someone will do this, and it will be reported.

Non-Compliance Lasts Forever (Or Almost)

The improper retention of funds is a difficult issue, especially since it is difficult to predict the course of the pandemic. Also problematic is the fact that HHS gives 30 days to return funds before accepting the terms and conditions, but it will take providers more than 30 days to accurately assess their real losses. Because of this, it has the potential to haunt providers through a False Claims Act whistleblower suit up to 10 years after the date of the allegedly improper retention. Further, a false or fraudulent act may occur each time an improperly-retained fund is used for a non-sanctioned purpose, which also could extend a provider's potential exposure to suit for years and years to come.

Further, providers must be careful not to let compliance slip in general. Many of the claims that we will see will either be comprised exclusively of, or include, claims unrelated to relief funding, such as improper billing/upcoding, medical necessity, excluded personnel (especially difficult to monitor with the hiring of workers during the emergency), Stark law violations, Anti-Kickback violations, etc.

Finally, it is important to remember that many whistleblower complaints are ultimately dismissed, not because the whistleblower was lying, but because the whistleblower was mistaken or misinformed. Even with the unsupported claim, the provider will run up expenses in responding to audits, subpoenas, and the defense of a suit. The best defense is a well-documented, on-message system of compliance that is effectively communicated throughout the organization.

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LDH's FAQs and Webinar on Relaxing Restrictions on Non-Emergency Healthcare Services
By Emily Black Grey

As a result of the COVID-19 crisis, the Louisiana Department of Health (LDH) issued multiple directives restricting non-emergency healthcare services. In an April 20 directive, LDH relaxed those restrictions, particularly for "time sensitive" services. On Friday, April 24, 2020, LDH provided FAQs. Additionally, the LDH Executive Counsel and State Health Officer presented a webinar that provided further helpful guidance for providers. This article summarizes the April 20 directive, the April 24 FAQs and the webinar recording.

APRIL 20, 2020 - LDH Healthcare Facility Notice #2020-COVID19-ALL-010
The first notice of relaxing COVID-19 came on April 20, 2020, the Department focused on: (1) Medical and Surgical Procedures, (2) Dental Procedures, and (3) Other Healthcare Services. The order became effective on Monday, April 27, 2020.

Medical & Surgical Procedures. Previously, in light of COVID-19, medical and surgical procedures were limited to those required for an emergency medical condition or where needed to avoid further harms. Under the new directive, providers can perform surgeries/procedures for **Time Sensitive Medical Conditions** where certain conditions are met, including where the provider/facility:

- Conducts a preoperative evaluation for COVID-19, including testing where available;
- Has a five-day supply of Personal Protective Equipment (PPE) on hand, an adequate supply chain for medical supplies and adequate medical & support staff;
- Contacts the patient within 10 to 14 days after the procedure to check for COVID-19; and
- Complies with the Centers for Medicare and Medicaid Services (CMS) recommendations and guidance including that of the April 19, 2020 regarding re-opening facilities to provide non-emergent, non-COVID-19 healthcare, also known as Phase I.

Dental Visits, Procedures & Surgeries. Similarly, dental providers may now treat for **time sensitive medical conditions** when certain conditions are met.

Healthcare Services, Other Than Medical & Surgical Procedures. Healthcare providers were previously directed to transition all in-person healthcare services to telehealth where medically appropriate and to postpone all in-person healthcare services that could safely be postponed for 30 days. The April 20 directive allows for the following:

- Providers should still **offer** telehealth rather than an in person visit when medically appropriate and the same standard of care can be met. Providers who have legitimate and valid barriers to telehealth delivery, who may not be able to shift all services to telehealth and who are acting in good faith shall not be found to be in violation of this directive.
- In-person healthcare services should be postponed when, in the provider's best medical judgment, patient outcomes will not be compromised.
- The facility/provider must contact the patient within 10 to 14 days to check for COVID-19. [*Note: this requirement was rescinded by later guidance*].
- The facility/provider should comply with CMS recommendations and guidance including that of April 19, 2020 regarding Re-opening Facilities to Provide Non-Emergent, Non-COVID-19 Healthcare: Phase I.

April 24, 2020 – LDH FAQs, Allowable Medical, Surgical & Dental Procedures Update

Additional clarifications from LDH on April 24, 2020 made notable changes to the earlier directive. Key points in the guidance include:

- **COVID Testing**: There is no requirement that **all** patients are tested before coming in for a procedure. Testing should be done for symptomatic patients.
- **Reduction of Follow-up Requirements**: Only facilities or providers who have performed an **invasive** medical, surgical or dental procedure are required to follow up with the patient 10 to 14 days after the procedure to inquire about COVID-19.
- **Preventative Procedures**: Preventative procedures (such as well child visits or dental cleanings) are considered time sensitive if performed with appropriate social distancing precautions.

April 24, 2020 – BSW Webinar with LDH Executive Counsel Stephen Russo & State Health Officer, Dr. Jimmy Guidry

In an April 24, 2020 webinar, hosted by Breazeale, Sachse and Wilson, LLP, the LDH Executive Counsel and State Health Officer provided additional guidance on these directives. Key points from the webinar include:

- Providers are given discretion as to whether a COVID-19 test needs to be conducted.
- The 10- to 14-day follow-up requirement is for invasive procedures only. Dr. Guidry recognized that the way the directive was written it appeared follow up was required for any encounter, but that is not what was intended. (*See* the webinar recording at 30:10).
- Dr. Guidry interprets invasive procedures as when one goes into a body cavity (not just the skin), such as through the peritoneum. A cortisone injection, pap smear or colonoscopy would not be considered invasive. This directive arises is based on evidence that COVID-19 patients have poorer outcomes, to ensure those patients heal properly. (*See* the webinar recording at 27:30).
- LDH views purely cosmetic procedures, (such as rhinoplasty, facelift, or eye lift) as not time sensitive, not an emergency medical condition, and not treatment of condition or disease.
- LDH views the 10- to 14-day follow up as the responsibility of the physician. However, the physician and facility can arrange for the facility to handle follow up on the physician's behalf.

- Dr. Guidry advised that telehealth should be offered to the patient, but if the patient wants to be seen in person or is not comfortable, they can go into the office. The provider should just make sure they are not in a full waiting room.
- The Attorney General's (AG) COVID-19 Task Force has addressed referrals of providers operating inappropriately. Stephen Russo explained that the AG was engaged for fact-finding in response to complaints because the usual LDH staff who investigates was busy with COVID-19 related tasks. He acknowledged that there was concern that there may be criminal potentiality involved, but that was not the case.

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