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The Honorable Greg Abbott  
Texas Attorney General  
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RQ-0227-GA

General Abbott:

I respectfully request an Attorney General's Opinion regarding immunity from liability for individuals administering vaccinations under the Conditions to Participation provided by the United States Department of Health and Human Services for participation in the Federal Medicare program.

**BACKGROUND**

The Centers for Medicare and Medicaid Services (CMS), an agency of the United States Department of Health and Human Services (HHS), formulates guidelines that healthcare providers must meet in order to participate in the federal Medicare program. These guidelines are known as Medicare's Conditions of Participation (CoPs). If a healthcare provider is in compliance with the CoPs, that provider becomes certified by Medicare and may then receive Medicare reimbursement for the healthcare services it provides to beneficiaries of the Medicare program. Hospitals may become Medicare-certified either through accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or through certification by state survey agencies, such as the Texas Department of Health (TDH). JCAHO and TDH use the CoPs as some of the standards by which to judge whether or not a facility will receive Medicare certification.

Recently, CMS removed from its CoPs the requirement that in a hospital setting, a physician must write an individual order for each influenza and pneumonia vaccination given to his or her patients in a hospital. These federal rules, found in 42 CFR Parts 482-84, became effective in October of 2002. Previously, the CoPs required a physician's order for immunizations in a hospital, although the regulations allowed the vaccination to be given without an order in such settings as a clinic or a doctor's office. Now, the

vaccines may be administered based on a physician-approved hospital protocol for a standing order after an assessment of contraindications. 42 CFR § 482.12(c) (2002). Standing orders are permanent entries placed in medical charts that require that the patient be told when it is time to get a vaccination and asked if he or she wants the vaccination. If the patient chooses to be immunized, the vaccination will be administered by the appropriate personnel without the need for the physician to write a new, individual order.

Preventative vaccines are a covered benefit of the Medicare program, but the immunizations rates are still considered too low by the federal government. Accordingly, CMS adopted the changes to the CoPs in order to facilitate the delivery of these vaccines in hospitals that serve Medicare patients. Influenza and pneumonia are considered the fifth leading cause of death for those aged 65 or over. CMS studies have shown that the use of standing orders is the most effective way to improve vaccinations among this age group.

But, administering these vaccines is not a common procedure in hospitals. Rather, immunizations are generally administered by family practice physicians in a physician office setting. Specialists, who are the physicians who typically would treat the hospital patients, are unfamiliar with the administration of immunization; their practices focus on treating a specific disease and not on preventative care or general wellness. Further, the nurses who work with these specialists in the hospital also are often unfamiliar with the administration of immunizations. And, when healthcare providers are unfamiliar with a procedure, they may be hesitant to proceed with it because of the looming threat of unknown liability for injuries that may come from the procedure. As such, many specialists will have strong reservations about giving these vaccines, even under the conditions provided for in the CoPs. Texas alleviates this concern of healthcare providers for certain vaccinations by providing immunity from liability under Section 161.001(a) of the Health & Safety Code when the vaccination is required by law or rule.

### **QUESTION PRESENTED**

Under Texas law, do the CoPs that hospitals must follow in order to participate in the Medicare program signify a “law or rule” that would ultimately provide the individual administering the vaccination immunity from liability for an injury that may be caused by the vaccination?

### **DISCUSSION**

In order to promote the health and well being of the patients in healthcare facilities, CMS has amended the CoPs to allow hospitals to use standing orders to administer vaccinations for influenza and pneumonia. Under the new regulations, if state law allows, appropriate non-physician personnel can provide these vaccines under a facility-approved standing-order protocol. 42 CFR § 482.23(c)(2) (2002) reads as follows:

**(c)(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under § 482.12(c) with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician approved hospital policy after an assessment for contraindications.**

But as with all healthcare procedures, there are risks of injury to a patient from the administration of a vaccine. In Texas, however, the legislature determined that the public health benefits of proper immunizations outweighed an individual's right to recover damages from such an injury by providing qualified immunity to individuals who administer certain vaccinations. Texas Health & Safety Code Ann. § 161.001(a) provides:

**(a) A person who administers or authorizes the administration of a vaccine or immunizing agent is not liable for an injury caused by the vaccine or immunizing agent if the immunization is required by the board or is otherwise required by law or rule.**

In order to fall under the protection of the state statute, the immunization must be required "by the board (TDH)" or "required by law or rule." *Id.* While the federal regulations do not mandate that hospitals have standing orders for influenza and pneumonia vaccinations, the change in the CoPs indicates CMS's intention to promote this kind of protocol in hospitals. CMS stops just short of a blanket rule that would absolutely require these standing orders, but in its comments to the regulations, CMS indicates the importance of administering these vaccinations. 42 CFR § 482.23(c)(2).

The CoPs provide the minimum standard with which hospitals must comply. These standards are used to improve the quality of care of Medicare beneficiaries. Accrediting agencies like JCAHO or TDH look to see if the facility has met and/or exceeded these requirements. See CMS website: <http://www.cms.hhs.gov/cop/>. For hospitals, the CoPs are the lifeblood of the facility; without strict adherence to these guidelines, a hospital may be sanctioned or even shut down. Thus, a permissive regulation such as Section 482.23(c)(2), can have the effect of explicit authority for hospitals trying to adhere to CMS' guidelines. If the CoPs were given such a weight under the Texas regulations, this would then provide physicians and hospital staff administering these vaccinations with limited liability for injuries caused by these vaccinations.

Further, the language in other Texas statutes seems to present a policy encouraging vaccination and cooperation by entities providing vaccinations. Texas Health & Safety Code Ann. § 161.0051(c) states that:

- (c) The board by rule shall require nursing homes to offer, in accordance with an immunization schedule adopted by the board:**
- (1) pneumococcal vaccine to elderly residents; and**
  - (2) influenza vaccine to elderly residents and to staff who are in contact with elderly residents.**

While this regulation applies to nursing homes and not hospitals, Texas recognizes these immunizations as important for the health of its older population. Further, the Texas Health & Safety Code § 161.010(b) states that “the department [TDH] shall increase coordination among public and private local, regional, and statewide entities that have an interest in immunizations,” and Texas Health & Safety Code § 161.004(a) requires “every child in the state shall be immunized against vaccine preventable diseases caused by infectious agents in accordance with the immunization schedule adopted by the board.” Under Texas Health & Safety Code § 161.001(a) the healthcare providers who administer these vaccinations are provided immunity. Though these particular statutes focus on the immunization of children, the regulation could be given a broad interpretation that embraces the policy of immunizing individuals against vaccine-preventable diseases, which would give force to the argument that the CoPs can be considered a “law or rule” that would, in turn, provide immunity for the qualified individuals who administer vaccinations through a standing order pursuant to CMS’s CoPs. It would seem counterproductive and against public policy to promote immunizations for one particular age group and not another. The language of these Texas statutes indicates that coordinated efforts should be made between public entities like the CMS and the state of Texas to increase the administration of influenza and pneumonia vaccinations through standing orders while under the protection of immunity for their administration.

In addition, the Texas Medical Foundation (TMF) uses the CoPs as the standard of care when evaluating the quality of medical care and health services for Medicare beneficiaries in Texas. TMF contracts with CMS to review quality of care issues in Texas hospitals. Since TMF must apply Medicare’s standards, the CoPs govern their decisions and have the force of law on the hospitals undergoing evaluations. Accordingly, TMF is currently reviewing hospitals and physicians for their compliance with providing the influenza and pneumonia vaccines regularly, pursuant to a standing order.

CMS research has shown that standing orders are effective to increase immunization rates, but the previous requirements on healthcare providers and hospitals interfered with their efforts to use them. Before this change to allow influenza and pneumonia vaccines without a written order was enacted, studies showed that the use of these vaccinations was hindered by (1) the requirement for the individual order from a physician, (2) the medical staff not viewing the vaccinations as a priority, and (3) the medical staff’s concern that a vaccination might interfere with patient’s course of treatment. The final rule was created to remove these barriers, to make it faster and easier for patients to receive influenza and pneumonia vaccinations, and to make the system more efficient and effective. These standing orders can ensure that many at-risk patients are informed about the benefits of these annual vaccinations and are given an opportunity to receive them.

**CONCLUSION**

There appears to be Texas statute that, if construed broadly, may embrace Medicare's CoPs as sufficient "law or rule" and provide limited liability to healthcare providers for injuries resulting from the administration of influenza and pneumonia vaccinations.

If you should have any questions, please feel free to contact me or John Paul Urban of my Capitol staff at (512) 463-0733.

I thank you for your time and consideration, and I await your response.

Sincerely,

A handwritten signature in cursive script that reads "Wayne Smith". The signature is written in black ink and is positioned above the typed name and title.

REP. WAYNE SMITH

Chairman

House Committee on County Affairs