

Insights and Commentary from Dentons

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HOMELAND SECURITY IS A REALITY

In the wake of the November 2002 elections and the subsequent adoption of the Homeland Security Act, homeland security has raced to the forefront of national policymaking, becoming a reality affecting all sectors of the economy, including the healthcare industry. An immediate concern confronting Georgia hospitals is the logistics and liabilities arising from immunizing employees with the smallpox vaccine.

NATIONAL STRATEGY FOR HOMELAND SECURITY

On November 13 and 19, 2002, respectively, the U.S. House of Representatives and Senate passed the Homeland Security Act of 2002, which establishes the framework for the Department of Homeland Security (“DHS”).¹ Although the Act establishes four distinct divisions within DHS, the division most affecting the hospital industry is Emergency Preparedness and Response.

Even prior to passage of the Homeland Security Act, Georgia created the Georgia Homeland Security Task Force (“GHSTF”) by Executive Order in October 2001. Comprised of representatives of six state offices and three associations representing Georgia’s first responders, GHSTF is charged with ensuring that Georgia is sufficiently prepared to respond to and recover from a large-scale terrorist attack.² In light of the recent warnings of attacks on hospitals, in the coming year look for DPH to plan the coordination of a statewide hospital response to potential bio-terrorism events.

THE EFFECT OF HOMELAND SECURITY INITIATIVES ON THE HEALTHCARE INDUSTRY

The healthcare industry already has been and will continue to be affected by homeland security initiatives on both the state and federal level. One aspect of homeland security that is expected to impact Georgia’s hospitals in the immediate future is President Bush’s proposed smallpox vaccination plan. The plan will be implemented in several stages, with the first stage providing for the inoculation of military troops deployed in high-risk areas. Next, the plan provides for the vaccination of approximately 500,000 emergency healthcare providers who face the greatest risk of exposure to smallpox, such as emergency room workers, infectious disease specialists, and intensive care workers. Thereafter, approximately 10 million police, firefighters, and other first responders will have access to the vaccination. Additionally, the Department of Health and Human Services (“HHS”) will coordinate with state and local governments to form Smallpox Response Teams and to provide public health services in the event of a smallpox outbreak.

In response to President Bush’s smallpox vaccination plan, Georgia has proposed a conservative approach to the vaccination of its healthcare professionals that follows the guidelines established by the Centers for Disease Control and Prevention. Georgia’s plan will be implemented in several stages. The

first stage calls for the vaccination of selected clinical personnel from public health and trauma centers in each of the established regions. To the extent possible, these regions mirror the Georgia Emergency Management Agency (“GEMA”) regions. One public health team from each region and approximately 10-15 employees per trauma center will be vaccinated, beginning with the GEMA region encompassing the metropolitan Atlanta area and the 7 trauma centers in the Atlanta area. Vaccinations then will be administered in the remaining regions and trauma centers. The second stage of Georgia’s plan calls for the vaccination of selected clinical personnel in the remaining acute care hospitals. The third stage of the plan allows for the vaccination of the general population, if an outbreak of smallpox occurs. All vaccinations will be voluntary based in part on concerns associated with the mortality and morbidity of the smallpox vaccination. At least one Georgia hospital, Grady Memorial Hospital in Atlanta, has announced that it will not inoculate its employees due to the risks associated with the smallpox vaccine.

Although Section 304 of the Homeland Security Act may provide hospitals with immunity from liability for the administration of smallpox vaccinations, it does so only (1) if the vaccination is administered by a licensed health professional authorized in Georgia to administer vaccines, (2) during the period of time the United States Secretary for HHS has declared that there exists a potential bioterrorist threat, and (3) if the individual receiving the vaccination was within the category of individuals covered by the declaration (or the qualified person administering the vaccine had reasonable grounds to believe that such individual was within such category). Given the limitations imposed by Section 304 and in light of the mortality and morbidity rates associated with the smallpox vaccination, Georgia’s hospitals and healthcare professionals may need to carefully consider several complicated issues including:

- The extent to which Section 304 of the Homeland Security Act provides immunity from liability to hospitals who provide the smallpox vaccination to its healthcare professionals.
- The extent to which Section 304 of the Homeland Security Act provides immunity from liability to hospitals who agree to have their staff vaccinated for smallpox, but do not administer the vaccine onsite or operate as a vaccination clinic.
- The standard for allowing the United States to seek subrogation against hospitals.
- Assurance that employees fall within the category of persons covered by the Secretary’s declaration.
- The level of informed consent required to administer the vaccination to those covered by a smallpox vaccination plan (and any potential liability associated with the issue of informed consent) to assure the hospital has not acted in a manner that constitutes gross negligence or reckless/willful misconduct.
- The extent to which hospitals are responsible for adverse event evaluation and treatment, and vaccination site management.
- The employment ramifications of a healthcare professional’s refusal to receive the vaccination.
- Funding for the vaccination and any subsequent medical care needed as a result of complications from the vaccination.³

As the smallpox vaccination plan demonstrates, the formation of DHS and the promulgation of new laws and regulations related to homeland security will have a major impact on hospitals, state and local governments, and universities and other research institutions in the United States. Proposed changes include the imposition of new reporting obligations, restrictions on hiring, industry product standards, security compliance requirements, and changes in the laws governing privacy. Companies and institutions will be required to conduct vulnerability assessments and compliance reviews, certify compliance with new government and industry standards, and also will be subject to compliance audits.

Changes to procurement rules, combined with vast new opportunities for federal contracts and grants, also will substantially alter the manner in which the government conducts its business. Although the regulations have not yet been written, there is no doubt that the Homeland Security Act will significantly affect hospitals in a multitude of ways and smallpox vaccinations are likely only the tip of the iceberg.

NOTES

1. The Act will result in the merger of all or part of the twenty-two federal agencies responsible for various aspects of homeland security into one centralized agency and will be headed by the new cabinet-level position, Secretary of Homeland Security. The Act is effective as of January 24, 2003.
 2. The GHSTF, in coordination with the Georgia Department of Human Resources, Division of Public Health (“DPH”): (1) worked to pass new legislation that clarified issues relating to vaccinations and quarantine authority in the event of a public health emergency, (2) developed specific plans for receiving and distributing the National Pharmaceutical Stockpile from the CDC for response to biological weapons incidents, and (3) devised statewide plans to support 19 public health districts, each of which will have a “Core Staff” including emergency coordinators and a trained epidemiologist to work with local first responders.
 3. As of December 5, 2002, the nation’s largest union of health workers announced that they will not oppose President Bush’s smallpox vaccination plan. However, union representatives have expressed concern about several issues, including responsibility for costs arising from complications related to the vaccination.
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CONTACT INFORMATION

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