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Health Law Developments

Michigan Legislature Streamlines Organ Donation Laws and Gives Patient Advocates Highest Priority

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Three new laws affecting organ donations were given immediate effect in Michigan as of July 22, 2003. They amend the Public Health Code provisions on anatomical gifts, and amend the Estates and Protected Individuals Code to allow a patient to include authority for anatomical gifts in a designation of patient advocate.

Key provisions of these laws include:

- Anatomical gifts made by a donor while alive either by will or by a document of gift cannot be revoked by anyone after the donor's death.
- If a donor has made a gift while alive, hospital representatives need not request consent from any one in the statutory priority list.
- The hospital organ donation log no longer need include the name and signature of the hospital representative making the request for an anatomical gift.
- In addition to gifts made by a uniform donor card, gifts may now be made by a signed statement on a driver's license or state identification card. The number of

required witnesses for these gifts has been reduced from two to one.

- A person who is unable to sign a document may authorize another to sign, if the signing and witnessing by one other person is completed in the presence of the donor.
- Patient advocates may be authorized in the designation of patient advocate to make anatomical gifts. An authorized patient advocate has first priority over all others in the statutory priority list, and that person's authority continues after the patient's death until the gift is made.
- A gift made by a person in a higher priority on the statutory list cannot be revoked by a person with a lower priority; however, a gift cannot be made by anyone with actual notice that a person in a higher or equal priority opposes, and no one with actual notice that the decedent expressed unwillingness has authority to make a gift.

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Can Your IRB Withstand FDA Scrutiny?



The Food and Drug Administration (“FDA”) is responsible for monitoring and evaluating the safety of human subjects involved in research. One way in which the FDA accomplishes this responsibility is by ensuring that each Institutional Review Board (“IRB”) complies with federal law and regulations as it reviews research involving FDA-regulated products. Recently the FDA has focused its reviews on non-teaching hospital IRBs, including facilities where relatively little research is being conducted. It is these smaller community hospitals, which review less than ten research protocols annually, that often forget the ongoing requirements applicable to IRBs.

Common Areas of Noncompliance

For example, many IRBs established policies, protocols and informed consent forms several years ago and have not updated the documents to reflect current practices. The membership of IRBs, particularly those that review only a small number of studies, often lack the diversity and professional representation required by the regulations. It is a challenge for hospitals with little activity to maintain IRB participation by the experts necessary to conduct appropriate review. These internal boards also can result in significant conflicts of interest—often the most experienced doctors are those who also conduct the research and seek IRB approval. Many IRBs have also failed to react to changes in federal laws affecting human subject research, such as HIPAA and federal reporting statutes.

Importance of Documentation

In our experience, when the FDA decides to audit an IRB, the FDA investigators assess compliance of the IRB not only with the regulatory requirements but also with the IRB’s own written policies and procedures. The IRB must conduct periodic meetings, maintain detailed minutes showing the members in attendance and the presence of a quorum, the votes taken and the rationale for the votes (whether approval or

disapproval). All conflicts of interest must be noted. The only way for the investigators to assess compliance is to review the documents maintained by the IRB. Therefore, it is critical that the IRB document all proceedings of the IRB, retain the documentation and make it accessible to FDA investigators conducting the audit. The IRB should have clear policies and procedures for emergency review, waiver of IRB review and any reviews involving special circumstances or hazardous products. The IRB may approve research (including continuing reviews) only at a meeting where a quorum is present. It is not sufficient for the IRB to meet only when there is a research protocol to be approved. The FDA also will review whether appropriate continuing reviews are performed, whether adverse events or incidents are adequately addressed and whether required reports are made to the appropriate government agencies.

Internal Compliance Review

If a facility has chosen to permit research to be conducted on its patients, the facility must establish and operate an IRB in compliance with federal regulations. There is no *de minimus* exception for facilities that only have a small amount of research activity. In fact, these types of facilities seem to be the target of current FDA scrutiny. As part of a facility’s ongoing compliance efforts, it is a good idea to include a review of IRB policies, procedures and ongoing operations to assess compliance with FDA regulations.

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Various CON Standards Subject to MDCH Public Hearing



Consistent with a draft policy released at the June 10, 2003 meeting of the Michigan Certificate of Need Commission, the Michigan Department of Community Health (“MDCH”) is moving forward with public hearings on four sets of CON review standards, namely Megavoltage Radiation

Therapy (“MRT”) Services/Unit, CT Scanning Units, Surgical Services, and Lithotripsy (UESWL). At the public hearing held on July 11, 2003, MDCH received the following comments on MRT and CT Scanning Standards.

MRT Standards

Public comment focused on (i) limited revisions to the “rural exception” for MRT services/units to address access issues in certain areas of the lower peninsula, and (ii) the development of a specific weighting factor of 2.0 for computing MRT equivalent treatment visits for intensity modulated radiation therapy (“IMRT”) procedures.

CT Standards

Public comments focused on revisions to the CT Standards to bring the standards into compliance with more current forms of CON Review Standards with specific provisions to address acquisition and relocation of existing CT units. Under the current Standards effective June 17, 1990, new CON approval is required to acquire an existing CT unit/service that is outside of a licensed health facility or to relocate an existing CT service. Public comments also focused on appropriate CON minimum volumes for combination PET scanning/CT scanning units and the addition of a specific definition of “replacement of a CT scanning unit.” Comments by the Michigan Health and Hospital Association and several providers also suggested changes to the CT Standards to permit small hospitals with a single CT scanner to replace an obsolete CT scanner even if CON minimum volumes have not been met.

A second public hearing was held on July 24, 2003 to address CON Standards for Surgical Services and Lithotripsy. We will report additional information regarding the specific testimony presented at this public hearing in the next newsletter.

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OFIS Commissioner Approved Modifications to BCBSM Provider Class Plan for Ambulatory Surgical Facilities



Effective June 30, 2003, the Commissioner of the Office of Financial and Insurance Services (“OFIS”), Michigan Department of Consumer & Industry Services, issued an Order approving modifications to the Blue Cross Blue Shield of Michigan Provider Class Plan (“Plan”) for Ambulatory Surgical Facilities (“ASFs”). The modifications to the Plan were approved after OFIS review of the modified Plan that BCBSM was required to file by April 1, 2003. The remedial Plan was required to include a revised method for determining eligibility for ASF participation with BCBSM that ensures an adequate, stable ASF network of providers. The modified Plan approved by OFIS includes five substantive modifications to the current Plan.

Revision 1

Permits a BCBSM-participating ASF temporarily to disable an operating room (“OR”) to meet the minimum per-OR volume requirements of 1,200 surgical cases or 1,600 hours of use per year requirement. It is anticipated that this change may help certain ASFs avoid “de-participation” from BCBSM due to inability to meet BCBSM minimum volume requirements. This revision does not permit a surgical facility seeking BCBSM participation to request certification of only a portion of total operating rooms within the facility.

Revision 2

Expands definition of “operating room” to include dedicated endoscopy and cystoscopy rooms. This change modified language in the existing Plan which potentially restricted surgical facilities with only endoscopy rooms from qualifying as a BCBSM ASF provider.

Revision 3

Expands the definition of “rural” to include facilities located in a county defined by the USDA as an “urban fringe” county if there are no other participating ASFs providing similar services within a 30-mile driving distance.



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As part of our service to you, we regularly compile short reports on new and interesting developments in health law and the issues the developments raise. Please recognize that these reports do not constitute legal advice and that we do not attempt to cover all such developments. Your comments on this newsletter, or any Dykema publication, are always welcome. © 2003 Dykema Gossett PLLC.

Revision 4

Clarifies that participating ASFs that add an OR will be granted a two year period of time to reach BCBSM minimum volume requirements.

Revision 5

Reduces the six-month volume requirement for new facilities to three months, but only in those counties where there is inadequate ASF capacity for BCBSM subscribers.

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Joanne Lax, a member of Dykema's HIPAA Task Force, appeared on WDIV's "Due Process" show on August 3, 2003 as a member of a panel discussing HIPAA's Privacy Rule. The show is intended to educate the public on important legal developments. The show may appear on other local stations throughout Michigan in the next several months.