New Notification Requirements for Pennsylvania Medical Providers

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As of December 23, 2018, Pennsylvania state law now contains new notification requirements for diagnostic imaging results. The Patient Test Result Information Act, 2018 Act 112 (the PTRIA), will require healthcare "entities" that perform various diagnostic imaging studies to directly notify patients (or their designees) within 20 days that a "significant abnormality" may have been identified. The statute does not apply to all diagnostic imaging and contains multiple exceptions. Generally, the notification requirements apply to "diagnostic imaging services," which the statute defines as a "medical imaging test performed on a patient that is intended to diagnose the presence or absence of a disease, including, but not limited to, a malignancy."

The PTRIA defines a "significant abnormality" as a "finding by a diagnostic imaging service of an abnormality or anomaly which would cause a reasonably prudent person to seek additional or follow-up medical care within three months." The statute further provides when an "entity" that performs diagnostic imaging services determines, in its judgment, that "a significant abnormality" ***may*** exist, the entity performing the diagnostic imaging service ***shall*** directly notify the patient or designee that the entity has completed a review of the test performed on the patient and has sent results to the healthcare practitioner who ordered the diagnostic imaging service. (emphasis added). The notice must be sent to the patient within 20 days after the test results were sent to the ordering provider and contain the following:

(1) The name of the ordering health care practitioner

(2) The date the test was performed

(3) The date the results were sent to the ordering health care practitioner

(4) The following statements:

> *You are receiving this notice as a result of a determination by your diagnostic imaging service that further discussions of your test results are warranted and would be beneficial to you.*
>
> *The complete results of your test or tests have been or will be sent to the healthcare practitioner that ordered the test or tests. It is recommended that you contact your healthcare practitioner to discuss your results as soon as possible.*

(5) The contact information necessary for the patient to obtain a full report.

Interestingly, the "entity" who performs the diagnostic imaging service is not required to provide the diagnostic report itself (although it is expressly permitted to do so if it chooses). The notification may be sent by U.S. Mail, email, automatic

alert from a medical record system, fax or provided to the patient at the time of the test. If the existence of a "significant abnormality" is conveyed in person, the patient must sign and acknowledge receipt of the information.

With respect to exceptions, the notice requirements do not apply to "diagnostic radiographs," which are essentially defined as two-dimensional x-rays. The notification requirements also do not apply to routine obstetrical ultrasounds to evaluate fetal development, nor do they apply to diagnostic imaging performed on emergency room patients or inpatients. Moreover, if the imaging results are communicated directly to the patient at the time the test is performed, additional written notification is not required.

At a minimum, the PTRIA creates additional responsibilities for healthcare "entities" that interpret diagnostic imaging (*e.g.*, hospitals, MRI centers, cardiology groups), over and above the typical practice of communicating the results to the ordering provider. There is medical sensibility in communicating test results to the ordering provider first, as many imaging results require clinical correlation to determine their significance. In other words, the ordering provider (like a primary care physician) may have additional information that puts the imaging results in proper context and allow the ordering provider to determine whether the patient indeed needs additional testing.

The PTRIA also raises the concern that radiologists or other "entities" governed by the notification provisions will feel pressured to "over call" findings to avoid potential liability under the Act. Although there may be some appeal to doctors "erring on the side of caution," the reality could be a situation where a multitude of patients are made to feel significant fear and anxiety that, in the judgment of the ordering provider, was ultimately unnecessary.

The statute contains other vagaries, such as how it will be enforced by the Pennsylvania Department of Health (DOH) and whether two dimensional x-rays were truly intended to be excluded from the notification requirements even when the images are suspicious for a fatal condition (*e.g.*, an incidental finding on an abdominal x-ray that may in fact be a malignancy).

As for enforcement by the state, the DOH recently accepted the recommendations of the Pennsylvania Medical Society and the Hospital and Healthcare Association of Pennsylvania to delay issuing fines or citations for noncompliance with the PTRIA for one year. During that time, the state will develop an educational campaign to prepare physicians for the new law.

However, the DOH also confirmed that "entities" must still establish a policy in accordance with the requirements the PTRIA, including how the entity will notify patients of "significant abnormalities." During the first year, if the DOH finds that an entity has failed to comply with the statute, it will issue a letter providing that facility with information to remedy the problem. The DOH will issue final clarifying guidance on or about December 23, 2019 with information concerning full implementation for PTRIA.

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