



Physician FAQs on the Patient Test Result Information Act

Nov. 15, 2018

Author: Michael D.I. Siget, JD, MPA, PAMED's Legislative & Regulatory Counsel

This document is general legal information and is not intended as legal advice. The law can change and is subject to differing interpretations. Physicians and patients should consult their own attorneys if they need legal guidance on a specific situation. Nothing in this document should be construed as defining a standard of care.

On Oct. 24, 2018, Gov. Tom Wolf signed Act 112 – known as the Patient Test Result Information Act – into law. This Pennsylvania law requires entities performing a diagnostic imaging service to directly notify the patient or patient's designee when, in the judgment of the entity performing the test, a significant abnormality may exist.

In this *Quick Consult*, PAMED answers physicians' frequently asked questions about the law.

1. When does Act 112 take effect?

Act 112 takes effect on Dec. 23, 2018.

2. Who does Act 112 apply to?

Act 112 applies to any entity that performs a diagnostic imaging service in which a significant abnormality may exist.

3. Who or what is an "entity" for purposes of Act 112?

"Entity" is not a defined term under Act 112. However, as Act 112 applies to any entity performing a diagnostic imaging service in which a significant abnormality may exist, an entity would likely include individuals or facilities performing such a service.

4. What is a "diagnostic imaging service"?

A diagnostic imaging service is defined 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."

5. What is a "significant abnormality"?

A significant abnormality is defined 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."



6. Does Act 112 only apply to radiologists?

No. Act 112 is not limited to radiologists. The law also applies to other health care practitioners.

7. Does Act 112 apply to health care facilities or just health care practitioners?

Both. Act 112 applies to “entities,” which likely would include both health care facilities and health care practitioners.

8. What is required if Act 112 is triggered?

The entity performing the diagnostic imaging service is required to directly notify the patient (or patient’s designee) by providing notice that the entity has completed a review of the test performed on the patient and the entity has sent the results to the ordering health care practitioner.

9. What triggers the requirements under Act 112?

Act 112 is triggered when, in the judgment of the entity performing a diagnostic imaging service, a significant abnormality may exist.

10. As judgment is required, does this mean I don’t have to send the notice if, in my judgment, a significant abnormality may not exist?

Under the plain language of Act 112, that is likely correct. However, the Department of Health has the authority to interpret this law in order to ensure compliance. Practitioners and entities should review the requirements of Act 112 and their existing professional obligations to determine what circumstances and results may trigger the Act 112 notice requirements.

11. If I am the ordering physician that also performs the diagnostic imaging service, am I still required to send the notice?

Not likely. A key component to Act 112 is to ensure that patients are kept informed of the results of their tests and that entities and ordering health care practitioners better understand their respective obligations. Act 112 applies to entities performing a diagnostic imaging service for a test ordered by a health care practitioner. If you are both the ordering physician and the entity performing the diagnostic imaging service, it is presumed that you will follow-up with the patient regarding the results of the test per your existing professional obligations.

12. What information is required to be in the notice?

The notice must include 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 statement: “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 health care practitioner that ordered the tests or tests. It is recommended that you contact your health care practitioner to discuss the results as soon as possible.”
5. The contact information necessary for the patient to obtain a full report.

13. Are there any exceptions under Act 112?

Yes. Notice is not required for the following services:

1. Routine obstetrical ultrasounds used to monitor the development of a fetus.
2. Diagnostic imaging services performed on a patient who is being treated on an inpatient basis or in an emergency room.
3. Diagnostic radiographs.

14. What is a “diagnostic radiograph”?

A diagnostic radiograph is defined as “a projectional radiograph that acquires an image or digital image with x-rays to produce a high contrast, two-dimensional image, otherwise known as an x-ray.”

15. If inpatients are an exception under Act 112, does this exception mean that hospitals are exempt from this law?

No. Hospitals and other providers that operate outpatient clinics or other facilities that perform diagnostic imaging services, wherein the patient is not admitted as an inpatient, will be required to comply with Act 112.

16. As the entity performing the diagnostic imaging service, am I required to send the test results to the patient under Act 112?

No. Only the information described above is required to be sent to the patient, which includes information on how the patient can obtain the full report from the diagnostic imaging service. However, Act 112 does authorize (but not mandate) the diagnostic imaging service to send the test results to the patient. Note that any other law or regulation that requires test results to be sent to a patient is still applicable.

17. Who must the test results be sent to?

The test results must be sent to the ordering health care practitioner.



18. What is the timeframe the notice must be sent to the patient?

The notice must be sent to the patient no later than 20 days after the date the test results were sent to the ordering health care practitioner.

19. What are the acceptable methods of communication of the notice to the patient?

Acceptable methods of communication are:

1. Mail in a properly addressed and stamped letter through the United States Postal Service.
2. Electronically sent by e-mail.
3. Sent by automatic alert from an electronic medical record system that the notice has been posted to the patient's electronic medical record that is presently viewable.
4. Sent by facsimile.
5. Provided directly to the patient at the time of service, so long as the patient acknowledges receipt of the results and signs the patient's medical record accordingly.

The notice shall be provided in a manner acceptable by the patient or the patient's designee. This means that if the patient requests a specific method of communication listed above, that request must be honored. If the patient does not specify a specific method of communication, then the entity performing the diagnostic imaging service may employ one or more of the communications listed above.

20. If I can hand the patient the notice, am I required to send an additional notice within 20 days?

No. If notice is handed directly to the patient at the time of the test, an additional notice is not required.

21. If I hand the patient the test results at the time of the test, am I still required to send a notice?

No. Act 112 does not require an entity to provide the notice if the results are provided to the patient or the patient's designee by the health care practitioner at the time of the test.

22. Can the entity performing the test provide a summary of the test to the patient?

Yes, though it is not mandatory. The entity performing the diagnostic imaging service may provide a summary of the diagnostic imaging service report (otherwise known as an impression or conclusion) or provide the complete results of the diagnostic imaging service provided to the ordering health care practitioner.

As of the date of this document, it is unknown whether providing the impression or conclusion to the patient negates the requirement to send the notice, as the law specifically negates sending the Act 112 notice if the test results are provided to the patient at the time of test, and is silent on whether providing the impression or



conclusion negates sending the Act 112 notice. Until the Department of Health provides clarification, it is recommended that practitioners and entities discuss this issue with their administrators and/or appropriate legal counsel.

23. After we send the notice, are we required to follow-up with the patient?

Act 112 only requires the notice to be sent. However, existing laws, regulations, and professional obligations would still apply, so practitioners should continue to follow those requirements and any policies in effect regarding following-up with patients or the ordering health care practitioner.

24. Who is charged with implementing Act 112?

The Department of Health will oversee implementation of Act 112.

25. What is the Department of Health's role regarding Act 112?

The Department of Health must conduct compliance reviews as part of its inspection or an inspection performed by an accrediting organization. The Department of Health must investigate complaints filed pursuant to a complaint procedure which it must make available on its website.

26. What are the penalties for failing to comply with Act 112?

At the time of this writing, it is unclear, as Act 112 does not specify penalties or what specific entities to whom the penalties will apply. However, as the Department of Health is charged with investigating complaints, it will have to determine penalties. It is also unclear at this time what role the state licensing boards will have under Act 112 for practitioners that violate Act 112's provisions.

27. Is there anything else we need to know about Act 112?

Yes. Nothing in Act 112 shall be construed as relieving a health care practitioner from complying with an existing professional obligation to inform a patient of test results.

28. What should we do to prepare for Act 112?

While PAMED is reaching out to the Department of Health for clarification on many aspects of this law, it is incumbent on facilities and practitioners to prepare for the Dec. 23, 2018 effective date of Act 112. We do not know what information we will receive from the Department of Health nor when that information will be conveyed. Therefore, it is highly recommended that all facilities and practitioners speak to their administrators and/or appropriate legal counsel to develop policies and procedures to implement Act 112.



29. Where can I obtain a copy of Act 112?

A copy can be accessed [here](#). Printer's No. 4107 is the enacted version of Act 112.

30. Where can I obtain additional information regarding Act 112?

PAMED has articles regarding Act 112 that can be accessed [here](#) and [here](#).

31. I want to contact the Department of Health myself. How can I do that?

You can contact the Department of Health at 1-877-PA-HEALTH or through its website [here](#).