Pennsylvania
Department of Health

The Patient Test Results Information Act
Act 112-2018
Clarifying Guidance
Updated September 2024

The Patient Test Results Information Act, Act 112-2018 (Act 112), was signed into law by Governor Wolf and became effective December 23, 2018. Act 112 requires that when, in the judgment of the entity performing the diagnostic imaging service, a significant abnormality may exist, the entity performing the diagnostic imaging service shall directly notify the patient or the patient's designee by providing notice that the entity has completed a review of the test performed on the patient and has sent results to the health care practitioner who ordered the diagnostic imaging service. The Department of Health (Department) announced in December 2018 that enforcement of Act 112 would be stayed for one year and citations for noncompliance with Act 112 would not be issued until December 23, 2019.

The Department received many questions regarding the implementation of Act 112 and concerns about its impact on providers. The Department will not be providing specific instructions about Act 112 implementation, rather, in determining compliance with this Act, the Department will require licensed facilities to establish a policy addressing implementation. The policy must include:

- How and when patients will be notified if a significant abnormality is identified on a diagnostic test;
- What information must be provided in the notification;
- What services the facility offers that fall within the Act's definition of "diagnostic imaging services;" and

Additionally, the Department will review a licensed facility's policies to verify that a patient's notification from the facility will include:

- The name of the ordering health care practitioner;
- The date the test was performed; and
- The date the results were sent to the ordering health care practitioner.

When determining whether a facility has implemented the requirements of Act 112, the Department will confirm that such a policy has been established and the Department will review whether the policy contains the above-mentioned criteria. Additionally, the Department will verify that the facility provided notification to patients identified with a significant abnormality in accordance with Act 112 and the facility's policy.

Please note, the Department does not have the authority to ensure compliance with Act 112 in facilities that are not required to be licensed under the Health Care Facilities Act. Act 112-related complaints received by the Department about a health care facility that is not licensed by the Department will be referred to the Department of State.

If there are any questions, please address them to the Deputy Secretary of Quality Assurance.

FREQUENTLY ASKED QUESTIONS
Act 112-2018
August 16, 2019

Q1. What is the definition of "diagnostic imaging services"? What services are considered diagnostic imaging services?

A1. A diagnostic imaging service is 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 Act applies to all diagnostic imaging services except: diagnostic radiographs, routine obstetrical ultrasounds used to monitor the development of a fetus, and diagnostic imaging performed in the inpatient setting or in the emergency room.

Q2. What is the definition of "significant abnormality"?

A2. A significant abnormality requiring an Act 112 notification is a finding that would cause a reasonably prudent person to seek additional or follow-up medical care within three months.

Q3. Does a patient in Observation Status receive a notice?

A3. No, patients in Observation Status would fall under the inpatient/emergency room exception of the Act, as described above.

Q4. If an entity provides a patient's diagnostic imaging test result with a patient at the time of the test, is the entity required to send a duplicate notification?

A4. No. An entity is not required to provide notice under the Act if the results are provided to the patient at the time of the test.

Alternatively, an entity may provide notice under the Act directly to the patient at the time of service, as long as the patient signs an acknowledgment of having received the notice.

Verbal notice that a significant abnormality may exist is insufficient.

Q5. The timeframe to send out the notice is "20 days after the date the results were sent to the ordering health care practitioner." Is that calendar days or business days?

A5. Calendar days.

Q6. What criteria will the Department of Health review to determine compliance with Act 112-2018?

A6. The Department requires a Department-licensed facility to establish a policy addressing the Act's requirements. The policy must include:

- How and when patients will be notified if a significant abnormality is identified on a diagnostic test;
- What information must be provided in the notification; and
- What services the facility offers that fall within the Act's definition of "diagnostic imaging services.

Additionally, the Department will review a licensed facility's policies to verify that a patient's notification from the facility will include:

- The name of the ordering health care practitioner;
- The date the test was performed; and
- The date the results were sent to the ordering health care practitioner.

When determining whether a facility has implemented the requirements of Act 112, the Department will confirm that such a policy has been established and review whether the policy contains the above-mentioned criteria. Additionally, the Department will verify the facility provided notification to patients identified with a significant abnormality in accordance with Act 112 and the facility's policy.

Entities that are required to provide notice under the Act but are not licensed by the Department must still meet the requirements of the Act. The Department will receive complaints related to failure to comply with the Act for all entities. The Department will refer complaints against entities not licensed by the Department to the appropriate state licensure board for investigation and enforcement.

Q7. Is a patient allowed to opt-out of receiving the required notice?

A7. No. The Act does not provide for patient opt-out.

Q8. In the event of an abnormality, who is responsible for notifying the patient?

A8. The entity performing the diagnostic imaging service is responsible for notifying the patient.

Q9. Is the patient notification required to include test results?

A9. No, but the entity must provide contact information to the patient for how to obtain a full report and the results must be sent to the health care practitioner who ordered the diagnostic imaging service.

Q10. If the patient does not speak English, does the notification have to be translated to their preferred language?

A10. Act 112 does not provide new requirements relating to notice to individuals with limited English proficiency, but the entity must still comply with any related Federal, state, and local laws.

Q11. Is notification of breast mammography results excluded from Act 112?

Q11. Yes. A mammogram is a diagnostic radiograph; and, therefore, exempt from the notification requirements of Act 112. However, the federal Mammography Quality Standards Act of 1992 and the Pennsylvania Breast Density Notification Act, Act 86 of 2013, requires patients to receive result notification and should continue to be followed.

Q12. How will the Department verify that notification was sent to the patient and what will the facility need to produce during the survey?

A12. The Department will request a list of patients that had a significant abnormality identified on a diagnostic imaging test within the past six (6) months. The Department will randomly select at least ten (10) patient records from that list and review the notification to verify it was sent to the patient and contains the proper information. Accordingly, facilities should maintain copies of the notifications required by Act 112 for at least six (6) months or in accordance with facility policy, whichever is longer.