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December 4, 2018

Rachel L. Levine, MD
Secretary of Health
Health & Welfare Building
625 Forster Street, 8th Floor West
Harrisburg, PA 17120

Re: Implementation of Act 112-2018

Dear Secretary Levine,

On behalf of the members of the Pennsylvania Medical Society (PAMED) and Hospital & Healthsystem Association of Pennsylvania (HAP), we are writing to you today concerning the Department of Health's (Department) implementation of the Patient Test Result Information Act (Act 112-2018).

As you are aware, Act 112 is set to take effect on December 23, 2018. Pursuant to the Act, specific events require entities performing diagnostic imaging services to send a notice to patients informing them that further discussions are needed with the practitioner who ordered a test that revealed a significant abnormality. Unfortunately, the language in the law leaves a lot of room for interpretation.

As the effective date of Act 112 draws closer, we have concerns that both facilities and practitioners are going to be left to decipher the Act and risk violating the law when they are attempting in good-faith to abide by its many requirements. What could result from these concerns is that patients receive unnecessary notices from diagnostic imaging services, which could cause unneeded worry and fear in these patients.

Over the past two weeks, representatives from your Policy Office kindly took the time to preliminarily discuss our concerns. To reiterate what we informed them, we have received numerous inquiries from our members over many facets of Act 112. While we are answering what questions we can, there are many questions that we are unable to answer because they require interpretation from the Department.

To mitigate the uncertainty created by the law, we are requesting that the Department consider two courses of action to ensure that facilities, practitioners, and patients are better prepared for the implementation of Act 112.

First, we are requesting that the Department allow stakeholders to submit questions to the Department for the Department to produce FAQ pages or other documents answering those questions.

The Department has solicited questions to develop FAQs in the past. In 2013, Act 122-2013 amended the Clinical Laboratory Act. As a result of these amendments, the Department received numerous questions from stakeholders.

In 2014, the Department published a notice in the Pennsylvania Bulletin inviting stakeholders to submit questions to the Department (see 44 Pa.B. 4029; June 29, 2014). The Department then answered those questions in a series of three FAQ documents. Those FAQ documents were well received by the

stakeholder community and ensured that laboratories would be better prepared to abide by Act 122. The FAQs still can be found on the Department's Bureau of Laboratories' website today.

Our second request mirrors an additional step that the Department took to implement Act 122 in 2014: delay issuing sanctions under Act 112 for a period of approximately one year.

Although the Department still began implementation of Act 122, the Department announced that it would delay sanctions under the Act for a period of approximately one year. The Department, concerned with how it was going to implement the Act as well as how stakeholders were going to comply, decided to launch an educational campaign regarding Act 122.

During this one-year period, when a complaint was filed against a laboratory which was found to have merit, the Department, instead of issuing sanctions, contacted laboratory personnel and educated them on the violations and how they could go about complying with Act 122 in the future. By the end of the one-year period, most of the questions and issues that arose when Act 122 was signed into law ceased and both the Department and stakeholders were better prepared going forward.

Given the many questions surrounding Act 112, we sincerely believe that delaying sanctions under Act 112 will have a similar effect on the proper implementation of the law for the Department and the stakeholder community. While delaying the issuance of sanctions may appear extreme, and the Department may have concerns about creating a precedent, history shows that the Department did this at least once before and that it was ultimately well-received and successful.

We urge the Department to consider both of our requests. Inviting stakeholders to a proverbial seat at the table will ensure better communication between the Department and stakeholders. It will also allow the Department time to consider and address any unforeseen issues.

In addition, it is imperative that stakeholders understand the Department's interpretation of Act 112 if stakeholders are expected to fully comply with its many requirements. By providing more information, the Department can ensure that the health and safety of the citizens of this Commonwealth remain at the forefront of this legislation.

Both HAP and PAMED stand ready to assist the Department in any way that we can, including communications with our members regarding actions the Department announces relative to Act 112, to ensure that stakeholders have the necessary information to comply with Act 112.

We look forward to hearing from you regarding our requests. Thank you for your service to the citizens of this Commonwealth.

Sincerely,

Martin P. Raniowski, MA
Executive Vice President
Pennsylvania Medical Society

Andy Carter
President & Chief Executive Officer
The Hospital & Healthsystem
Association of Pennsylvania

cc: Tom Wolf, Governor, Commonwealth of Pennsylvania
Mike Turzai, Speaker, House of Representatives
Bryan Cutler, Majority Leader, House of Representatives
Frank Dermody, Minority Leader, House of Representatives
Joseph Scarnati, III, President Pro Tempore, Senate
Jake Corman, Majority Leader, Senate
Jay Costa, Minority Leader, Senate