



UTAH SOCIETY OF
HEALTH-SYSTEM PHARMACISTS

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It's the End of the World As We Know It?: COVID-19's Regulatory and Policy Impacts

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Disclosure

Instructions:

I have no conflicts to disclose and I will not be discussing off-label uses of drugs.



Learning Objectives

- At the conclusion of this activity, *pharmacists* should be able to successfully:
 - Differentiate between federal COVID-19 regulatory changes that are permanent versus those that are temporary;
 - Identify challenges to expanded pharmacist authority for COVID-19 testing and payment for telehealth services;
 - Assess the impact of federal COVID-19 regulatory changes on his/her practice.



Learning Objectives

- At the conclusion of this activity, ***pharmacy technicians*** should be able to successfully:
 - Identify federal COVID-19 regulatory changes/waivers that impact his/her working environment;
 - Analyze how pharmacy technicians may engage in new COVID-19 testing models;
 - Assess potential challenges to fully utilizing new COVID-19 regulatory flexibility.



COVID-19 Regulatory Flexibility



Telehealth
Supervision
Requirements
Enhanced Payment

Compounding
Hospital/Health
System Guidance
Emergency Use
Authorizations

Flexible Annual
Production Quota
(APQ) Allocation
Temporary Site
Registration

What Stays and What Goes?

- Agencies have invited extensive stakeholder feedback on which flexibilities they should make permanent.
- CMS has been the most forthcoming about plans to make certain flexibilities permanent, while DEA was fairly clear from the start that most, if not all, of the flexibilities it has provided during the PHE are temporary.
- Determining when to phase out temporary policies will likely be a major area of contention going into 2021.

CMS Flexibilities

1

Telehealth

At least some aspects of the telehealth policies are going to be permanent.

2

Supervision

CMS has indicated that it will continue to allow for virtual supervision of Physician Fee Schedule services through 2021, but has not yet committed to it permanently.

3

COVID-19 Testing and Immunizations

HHS used PREP Act authority to allow pharmacists to provide COVID-19 testing, and now PREP Act has been used to allow pharmacists to provide pediatric immunizations.

CMS Flexibility: Telehealth

- CMS has created extensive regulatory flexibility in response to COVID-19, with an emphasis on making telehealth available
- Pharmacists cannot bill directly for telehealth, but can bill under incident-to models
 - We continue to request clarification from CMS about the allowable levels of E/M coding for incident to services
- Limited to the codes that CMS has listed on its website, although the agency intends to add to the list regularly

Major Changes to Medicare Telehealth Policy

- Changes took effect for visits as of March 6, 2020
- Patients may be either a new or established patient
- These visits are the same services as would be provided during in-person visit and are paid at the same rate as in-person visits
- The patient may be located in any geographic location (not just those designated as rural), in any healthcare facility, or in their home
- The Medicare coinsurance and deductible would generally apply to these services; however, the HHS Office of the Inspector General is providing flexibility for healthcare providers to reduce or waive cost-sharing for telehealth visits paid by federal healthcare programs

CMS Flexibility: Supervision

- Medicare Physician Supervision requirements:
 - For services requiring direct supervision by the physician or other practitioner, that physician supervision can be provided virtually using real-time audio/video technology
- In practice, this makes it look more general supervision, which is the rule for hospitals and outpatient departments
- Allows far more flexibility in setting up care delivery models
- CMS recently announced that it will extend this policy into 2021, but remains on the fence about making it permanent

CMS Flexibility: Pharmacist-Provided COVID-19 Testing

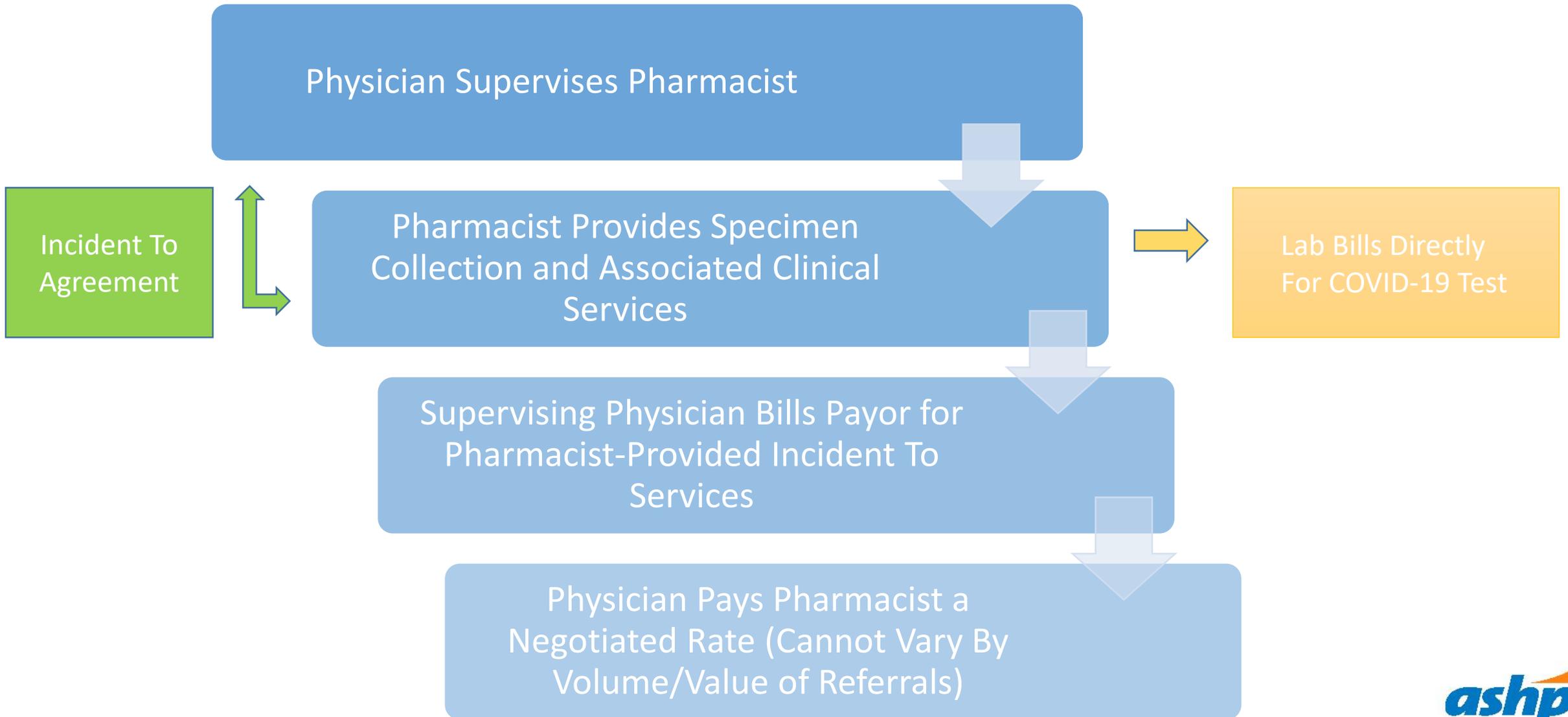
- Physicians do not have the capacity to perform all COVID-19 testing
- Creating an incident to billing relationship, which will require either that both providers share an employer (e.g., in a clinic) or through a contract with a physician and a pharmacist, expands testing access
- Creation of a new contractual arrangement might seem daunting, but is similar in nature to a collaborative practice arrangement – in fact, CMS does not mandate specific contractual language for incident-to relationships

Audience Question #1:

CMS has announced that all of the telehealth flexibilities rolled out during the public health emergency will be permanent:

- A. True
- B. False

Pharmacist-Provided COVID-19 Testing and Payment



CMS Flexibility: Pediatric and COVID-19 Immunizations

- HHS used authority under the Public Readiness and Emergency Preparedness (PREP) Act to allow pharmacists to provide ACIP-recommended pediatric vaccines during the public health emergency
- Concern had been increasing that the pediatric immunization rates were suffering because of COVID-19
- Payment has yet to be determined

Pediatric Immunizations – Strings Attached

1

Follow ACIP Schedule

Provide the immunization on ACIP's standard vaccination schedule.

2

Complete 20 Hours of ACPE Practical Training

Must include "hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines."

3

Maintain CPR Certification

Must be current in basic cardiopulmonary resuscitation

4

Complete ACPE-Accredited Immunization CPE

Must complete a minimum of two hours of focused CPE during each state licensing period.

5

Comply with Recordkeeping and Reporting

Must comply with an extensive list of requirements, including "informing the patient's primary care provider when available."

6

Discuss Well-Child Visit

Inform "his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate."

Audience Question #2

Pharmacists can now provide (and be reimbursed for) all pediatric vaccines:

- A. True
- B. False

FDA Flexibilities



- Extensive 503A and 503B compounding flexibilities
- Explicit statement that draft Hospital and Health System Guidance would not be enforced
- Oversight of the Emergency Use Authorizations; Involvement in Distribution Plans

Compounding Flexibilities

- FDA announced that it will not be enforcing the “one-mile radius” from the Hospital and Health-System Draft Guidance
- FDA provided a number of additional regulatory flexibilities in response to COVID-19:
 - Allowing 503Bs and 503As to compound products that are in short supply provided they are for treatment of hospitalized COVID-19 patients
 - Revising BUD dates for certain products compounded for hospitalized COVID-19 patients
- These policies are temporary – the big question is when FDA will start the rescission process

Emergency Use Authorizations

- Current EUAs for COVID-19 include remdesivir and diagnostic and antibody tests
- Related to testing, HHS just revoked all existing guidances regarding laboratory developed tests and announced they would not reinstate LDT oversight without notice-and-comment rulemaking or new legislation
- Granting and then revoking hydroxychloroquine EUA may leave lasting scars on FDA (from both sides of the aisle)

Directing Supply

- FDA played a limited role in the initial distribution of remdesivir
- Initial remdesivir distribution was chaotic, with some hospitals receiving supply they hadn't expected with limited guidance about how they could use or share it
- Coordination between the HHS subagencies seems to have improved over time, but there are still sticky areas

Audience Question #3

FDA has allow temporary flexibility for which of the following:

- A. Extending BUDs for certain products compounded for hospitalized patients
- B. Compounding of products in short supply for hospitalized patients
- C. Using 503A facilities to compound products for COVID-19 patients
- D. All of the above

DEA Flexibilities

1

Worked with ASHP and other stakeholders to quickly increase the allocation of annual production quotas for CII used for mechanical ventilation

2

Allowed hospitals to send CII to temporary expansion sites created in response to COVID-19

3

Met regularly with ASHP and other stakeholders to ensure they had taken steps to protect the supply chain



What's Next?

- Next battle lines will be around rolling back flexibilities that agencies consider temporary
- If flu season and COVID-19 collide, the agencies are likely to extend flexibilities and even consider new ones if the situation on the ground markedly disintegrates
- Preparing for the COVID-19 vaccination campaign



Questions?

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