COVID-19 TESTING: AN EXAMINATION OF RELEVANT FEDERAL AND STATE LAWS AND THE COMPLIANCE RISKS FOR THOSE INVOLVED

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COVID-19 TESTING: RELEVANT LAWS, RULES AND GUIDANCE

FDA REGULATIONS

- Emergency Use Authorizations for COVID-19 PCR and Antibody Tests
  - "Authorized" vs "Approved"
- FDA has issued industry guidance and updated several times.
  - NOTE: Non-Binding Guidance

FDA REGULATIONS

Lab-Developed Tests

- Must be CLIA-Certified for High Complexity Testing.
- Must submit to FDA an EUA request within reasonable time (i.e. 15 days) after begin implementing UNLESS your state has elected (e.g. NY) to be responsible for authorizing lab-developed tests under their own state law.
- FDA has an EUA template on its website.
- FDA won't object to use of test pending EUA approval as long as its preliminary review of submitted data is found acceptable.
- FDA recommends that labs obtain confirmation of the first five positive and the first five negative clinical specimens using an EUA-authorized assay.

FDA REGULATIONS

Commercially-Developed Tests

- **EUA**: Must have an EUA to distribute tests in the U.S.
- **IFU**: A manufacturer can distribute their test if it is labeled consistently with the labeling authorized by FDA, including the particular test's instructions for use ("IFU").
  - EUAs, and their IFUs outline the conditions under which a manufacturer can distribute their tests, and the specific equipment and methodologies that are required to be used by laboratories processing such tests.
  - All commercially-manufactured COVID-19 tests are labeled as "Rx Only". So, under FDA law, there has to be a valid prescription for these tests.

FDA REGULATIONS

Commercially-Developed Tests

- **AMENDING AN EUA**:
  - **REQUIRED:** When changing specimen type (e.g. from nasopharyngeal swab to saliva).
  - **OPTIONAL:** Outside of changing specimen type, if modifying an EUA-authorized test, one does not need to notify the FDA or amend an EUA as long as "the modified test is validated using a bridging study to the EUA-authorized test. One way to bridge to a new component is to establish equivalent performance between parallel testing of the same specimens with the new and original components."

PROBLEMS

- **If a laboratory modifies an EUA-authorized test (e.g. extraction method, transport media), then their testing processes and methodologies don't line up with the EUA and the IFU.**
  - CLIA compliance?
- **All commercially EUA COVID-19 tests are Rx Only.**
  - What about testing that is being conducted by state agencies, without an Rx?
    - Some states have issued a state-wide standing order for these tests to solve for this issue. Others have not.

CLIA

- **Overview:** The Clinical Laboratory Improvement Amendments (CLIA) regulate laboratory testing and require clinical laboratories to be certified by CMS before they can accept human samples for diagnostic testing. Labs can obtain multiple types of CLIA certificates, based on the kinds of diagnostic tests they conduct.
- FDA, CMS and CDC are all involved in CLIA.
- **CMS is responsible for issuing CLIA certificates, inspections and regulatory enforcement**
  - However, CMS has no authority to waive CLIA requirements.
- CMS contracts with state agencies (e.g. in Utah, the Utah Public Health Laboratory, a division of the Utah Department of Health) to conduct CLIA surveys, investigations, etc.

CMS AND CLIA ENFORCEMENT

- **CMS officials have publicly asserted they will be flexible and assert enforcement discretion:**
  - "During this state of emergency, CMS's inspection efforts are focused primarily on addressing immediate jeopardy situations, and CMS is generally exercising enforcement discretion for activities that do not rise to that level."
    - See CLIA Laboratory Guidance to State Survey Agency Directors
  - While it does not have statutory authority to waive CLIA requirements, it will exercise enforcement discretion and, where possible, "is willing to explore flexibilities…" (See: FAQs, CLIA Guidance During the COVID-19 Emergency)

CMS AND CLIA ENFORCEMENT

- **Related to specific CLIA forms/requirements and COVID-19 Testing:**
  - CMS published a summary related to changes implemented in response to COVID-19, acknowledging that its current CLIA forms require changes to accommodate the present realities (e.g. "documentation and record keeping requirements for lab tests that would not be relevant in the absence of a treating physician's or NPP's order.") See: https://www.cms.gov/files/document/r10160otn.pdf
  - CMS issued guidance to State Surveyor Agency Directors on March 26, 2020, related to CLIA enforcement during the COVID-19 pandemic. Therein, CMS states:

    Alternate Specimen Collection Devices

    > *CLIA regulations are not prescriptive about the type of transport device, for example, specimen collection swabs and viral transport media, that laboratories use to collect the specimens needed to perform a tes*t. CLIA only requires that the laboratory follow manufacturer's instructions. If a laboratory modifies the manufacturer's instructions, the laboratory must establish performance specifications and validate the assay prior to performing patient testing. *CLIA is not prescriptive as to how the study is performed*;

    Emphasis added. Found here.

PROBLEMS

- Despite CMS's statements, strict CLIA enforcement is occurring.
- CMS's guidance to its State Survey Agency Directors related to COVID-19 testing and CLIA enforcement is not being followed.
  - Misunderstanding?
  - Disconnect between CMS and contracted State enforcement officials?
- State Survey Agency Directors and/or CMS officials involved in CLIA enforcement are trying to interpret and enforce FDA guidance related to COVID-19 testing (even though it is non-binding and outside the scope of CLIA)
  - Need for better interagency communication and cooperation?

CLIA INTERIM FINAL RULE

- Pursuant to the CARES Act, as of August 25, 2020, CMS modified CLIA to require certified laboratories that perform or analyze any test that is intended to detect or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) are required to report the results (both positive and negative) within 24 hours of being known.
- Health care facilities using Point of Care COVID-19 testing devices under a CLIA Certificate of Waiver, including nursing homes, pharmacies, or other settings are be required to report test results under this regulation.
- Failure to follow subjects one to civil monetary penalties.
- Guidance for reporting is found here.

BOTTOM LINE

- Despite CMS's statements, assume strict enforcement of CLIA requirements.
- Assume the lab will be held accountable for all aspects of COVID-19 testing, in conformity with CLIA Standards/Conditions, from specimen collection, transportation, storage, and test reporting.
- Even where a state or government agency is conducting COVID-19 testing and wants to institute their own protocols and technologies, the Lab is the one responsible for all aspects of testing and everyone involved must be following the Lab's SOPs.

REIMBURSEMENT: APPLICABLE LAW

Families First Coronavirus Response Act ("FFCRA")

- Effective 3/18/2020
- Requires coverage of diagnostic COVID-19 testing, including related items and services
- Prohibits cost-sharing, prior authorization or other medical management requirements

Coronavirus Aid, Relief and Economic Security Act ("CARES Act")

- Effective 3/27/2020
- Amended FFCRA to include additional diagnostic items and services that must be covered

PRIVATE PAYORS

What insurers are impacted?

- Group health plans (self-insured and insured)
  - Employment-based health plans (ERISA plans)
  - Non-federal governmental plans
  - Church plans
- Individual plans
- Student health insurance

PRIVATE PAYORS (CONT'D)

General Requirements:

1. Must cover in vitro diagnostic tests and their administration.

2. Must cover items and services furnished to a patient during a provider visit that results in an order for or administration of an in vitro diagnostic test.

3. Must not impose any cost-sharing, prior authorization, or other medical management requirements.

PRIVATE PAYORS (CONT'D)

1. **Must cover in vitro diagnostic tests and their administration.**

   – PCR, Antigen, Serology/Antibody
   – Must be either
     - FDA approved, cleared, or authorized (listed on FDA website); or
     - EUA will be or has been requested (listed on FDA website); or
     - Authorized by State, pursuant to HHS notification (listed on FDA website); or
     - Determined appropriate by HHS
   – Includes At-Home Tests

PRIVATE PAYORS (CONT'D)

2. **Must cover items and services furnished to a patient during a provider visit that results in an order for or administration of an in vitro diagnostic test.**

   - Required to the extent the other items and services relate to the furnishing of a test or evaluation of the individual

   - Visit is defined broadly to include traditional and non-traditional care settings, including drive-through screening and testing sites where providers are administering tests

   - Diagnostic laboratory tests for other respiratory illnesses (e.g., influenza, RSV), X-rays, blood tests, facility fees

PRIVATE PAYORS (CONT'D)

3. **Must not impose any cost-sharing, prior authorization, or other medical management requirements.**

   – Must cover COVID-19 diagnostic testing and related items/services in full when
      i. determined **medically appropriate** for the individual
      ii. by the individual's **attending healthcare provider**
      iii. in accordance with **accepted standards of current medical practice**
      iv. based upon an **individualized clinical assessment**.

   – No limit on number of tests

PRIVATE PAYORS (CONT'D)

What about public health surveillance testing or employment screening?

PRIVATE PAYORS (CONT'D)

How much are payors required to pay?

- Payors will generally reimburse in-network providers at negotiated rates.

- Payors must reimburse out-of-network providers an amount equal to the cash price that the provider has published on their website.
  - Providers are required to publish the cash price for the COVID-19 diagnostic test by the CARES Act, and can be subject to civil monetary penalties imposed by HHS for non-compliance.
  - See https://www.cms.gov/files/document/covid-ffs-price-transparency-faqs.pdf

PRIVATE PAYORS (CONT'D)

How long are plans required to comply with these requirements?

- Applies to items and services provided on or after March 18, 2020
- Lasts, at a minimum, through the end of PHE

PRIVATE PAYORS (CONT'D)

Nothing prevents a state from imposing additional standards or requirements on health insurance issuers.

Utah Insurance Department, Bulletin 2020-16 (August 12, 2020)
- https://insurance.utah.gov/wp-content/uploads/2020-16Signed.pdf

Idaho Department of Insurance, Bulletin No. 20-13 (July 10, 2020)
- https://doi.idaho.gov/DisplayPDF?Id=7986

Colorado Division of Insurance, Bulletin No. B-4, 108 (April 30, 2020)
- https://drive.google.com/file/d/1Cnwci8Z4A1FZoMGk3zdI1mLfiOgTntvu/view

PRIVATE PAYORS (CONT'D)

Joint Agency FAQs

- April 11, 2020
  - https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf
- June 23, 2020
  - https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf

GOVERNMENT PAYORS

What is covered?

- In vitro COVID-19 Diagnostic Tests
- Reasonable and necessary
  - Beneficiary with known or suspected current or prior COVID-19 infection. 42 CFR 410.32(a)(3).
  - Must be "medically necessary" in the course of establishing or ruling out a COVID-19 diagnosis, or identifying patients with an adaptive immune response, recent or prior infection.
- No coverage for "return to work" programs, public health surveillance testing, or any other non-diagnostic purpose.

GOVERNMENT PAYORS (CONT'D)

What is covered?

- Other Diagnostic Laboratory Tests
  - Covered influenza and RSV clinical diagnostic lab tests, see https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf for codes.
- Diagnostic X-ray
- Counseling given to patients on the importance of self-isolation after testing and prior to the onset of symptoms.

GOVERNMENT PAYORS (CONT'D)

Is an order required?

- Effective 9/2/2020, only 1 COVID-19 diagnostic test and 1 of each other related test will be covered *without* an order from a physician or other practitioner. 42 CFR 410.32(a)(3).

Who can order?

- NPs, NCSs, PAs, and CNMs can order, furnish directly, and supervise performance of diagnostic tests, subject to applicable state law. CMS-5531-IFC.
- Pharmacist or other healthcare professional authorized to order diagnostic lab tests per state law. CMS-3401-IFC.
- Must directly notify the patient of the results

GOVERNMENT PAYORS (CONT'D)

What about coverage for required testing in long-term care facilities?

- Coverage is consistent with CDC Testing Guidelines for Nursing Homes
  - https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html
- Payment Flowchart for COVID-19 Testing in LTC Facilities:
  - https://www.cms.gov/files/document/covid-medicare-payment-covid-19-viral-testing-flow-chart.pdf

GOVERNMENT PAYORS (CONT'D)

What are the applicable dates for coverage?

- Items or services furnished on or after 3/18/2020, and during the applicable emergency period

More information about Medicare billing:

- COVID-19 FAQs on Medicare FFS Billing
  - https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

UNINSURED PATIENTS

- Medicaid
  - FFCRA and CARES Act added a new optional Medicaid eligibility group for uninsured individuals, effective 3/18/2020
    - For more information on limited benefit package, see https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-CARES-faqs.pdf
- HRSA Claims Reimbursement
  - COVID-19 testing and testing-related visits on or after 2/4/2020.
  - Reimbursed at Medicare rates
- Provider Relief Funds

CLAIM SUBMISSION TIPS

Tips:

- Work with your payors in advance of claim submission to identify documentation requirements.
  - Medical appropriateness / medical necessity
  - Information about COVID-19 test used
- Ensure you are using appropriate claim codes and modifiers in accordance with state and federal laws and payor reimbursement policies.
  - Consider place of service, type of test administered, other items/services administered.
- Monitor for new CPT, HCPCS, ICD-CM codes and guidance from private payors, state Medicaid, and MACs.

THANK YOU

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