Welcome and Introductions

Wednesday, August 11, 2021

Allen Jansen
Senior Deputy Director
Behavioral Health and Developmental Disabilities

This week's trending conversations

- Home closures due to staffing crisis

Today's topics and guests

- **Support for AFC-HFA Disaster Planning**
  Wendy Snyder, MSN, RN, ED
  Bureau of EMS Trauma and Preparedness

- **Understanding FDA COVID Testing Changes**
  Dr. Marty Soehnlen, PhD, MPH, PHLD (ABB)
  Infectious Disease Division, Bureau of Laboratories

AFC/HFA Statewide All – Hazards Planning Committee

Bureau of EMS Trauma and Preparedness

Wendy Snyder, MSN, RN, ED

08/11/2021

Background

- All Hazards Emergency Preparedness approach, that will support and strengthen Adult Foster Care (AFC) facilities and Homes for the Aged (HFA) disaster planning throughout the state of Michigan. The COVID-19 Pandemic has enlightened many, stretching emergency preparedness to its max!
- Developed in February 2021 as a result of lessons learned from COVID -19 Pandemic response. The goal is to ensure the bridging of those gaps moving forward.
- State level, Interdepartmental approach

Process

Polled subject matter experts to determine gaps in emergency preparedness.

- Triggers and planning considerations to create a proactive response
- Client Placement – who, what, where, and how
- First line of contact for placement of behavioral health residents.
- Reimbursement
- Etc, etc, etc.

Ongoing Survey

Survey has been sent to AFC/HFA: the survey closes out on 08/13/2021

- Contact information
  - Facility type, number of facilities, number of employees
- Requests of the state
  - PPE Needs/requirements
  - Information/assistance education and training
  - Information/assistance evacuation/shelter in place
  - Emergency plan development
- Lessons learned from Covid - 19
  - What are the primary concerns/issues/gaps

Helpful Tools and Resources

Job action sheet

- MIOSHA links and emergency telephone numbers
  - Local health department, local ombudsman, regional healthcare coalitions, local emergency manager, Licensing and Regulatory Affairs (LARA), Bureau of EMS, Trauma, & Preparedness (BETP), Community Mental Health
  - Includes information regarding emergency planning and preparedness checklist

Current plans cont'd

- Template for emergency preparedness planning
  - Will be in PDF form as well as online
  - Template breaks down AFC/HFA by size and type
  - Emergency preparedness requirements per licensing agency
  - Tool kit provided
- Train the trainer education related to emergency preparedness
- Generate a new administrator on-boarding packet

Emergency Planning Website for AFC/HFA

- Website is live
  - MDHHS - Adult Foster Care & Homes for the Aged Emergency Planning (michigan.gov)
  - Template for emergency planning to be added to website

QUESTIONS?

Understanding the FDA COVID Testing Changes

Marty K. Soehnlen, PhD, MPH, PHLD(ABB)

Laboratory Community

260,000

LABORATORIES IN USA

13 BILLION

tests per year

That's 40 tests per year for every person living in the United States

Lab Personnel 800,000

Important Facts of Regulatory Bodies

- CMS is the Centers for Medicare and Medicaid Services
  - Formed in 1965
  - Has some aspects of control over hospitals, laboratories, outpatient clinics, SNFs, pharmacies, hospice, ambulatory services, and any service that bills Medicare or Medicaid
- Regulatory bodies have the authority to penalize for infractions
  - Fines
  - Probation
  - Unable to bill
  - Shutdown
- Only impacts the areas that legally are applied to their realm
  - Example:
    - FDA – regulates fish, but not catfish
    - USDA – regulates meat and catfish

High Complexity Tests

Tests that are the most difficult to perform or are subject to the most error

Generally only performed by large clinical labs

Requires QA, QC, PT, and stricter personnel requirements

Most molecular tests including RT-PCR, chip arrays, multiplexed analyses, viral loads, expression arrays, and sequencing are high complexity

Examples of Regulatory Bodies

- CMS (medical and lab)
  - CLIA (lab)
- FDA (medical devices, food, cosmetics, etc.)
- EPA (water)
- OSHA (blood-borne pathogens, etc.)
- USDA (food)
- DOT (packaging and shipping of hazardous materials)
- Federal Select Agent Program (high consequence pathogens)

CMS and FDA friendship

- FDA decides if device (test) is “safe and effective”
- CMS decides if item if service is “reasonable and necessary”

- Commercially available lab tests are considered “in-vitro diagnostic devices”
- Class 1 – minimal potential for harm (ex. Point of Care Tests)
- Class 2- general controls not sufficient so need pre-market review (more advanced instruments for chemistries or Complete Blood Counts)
- Class 3 – new or not enough info about safety, most stringent category so needs pre-market approval (ex. Hepatitis B or C, cancer tests)

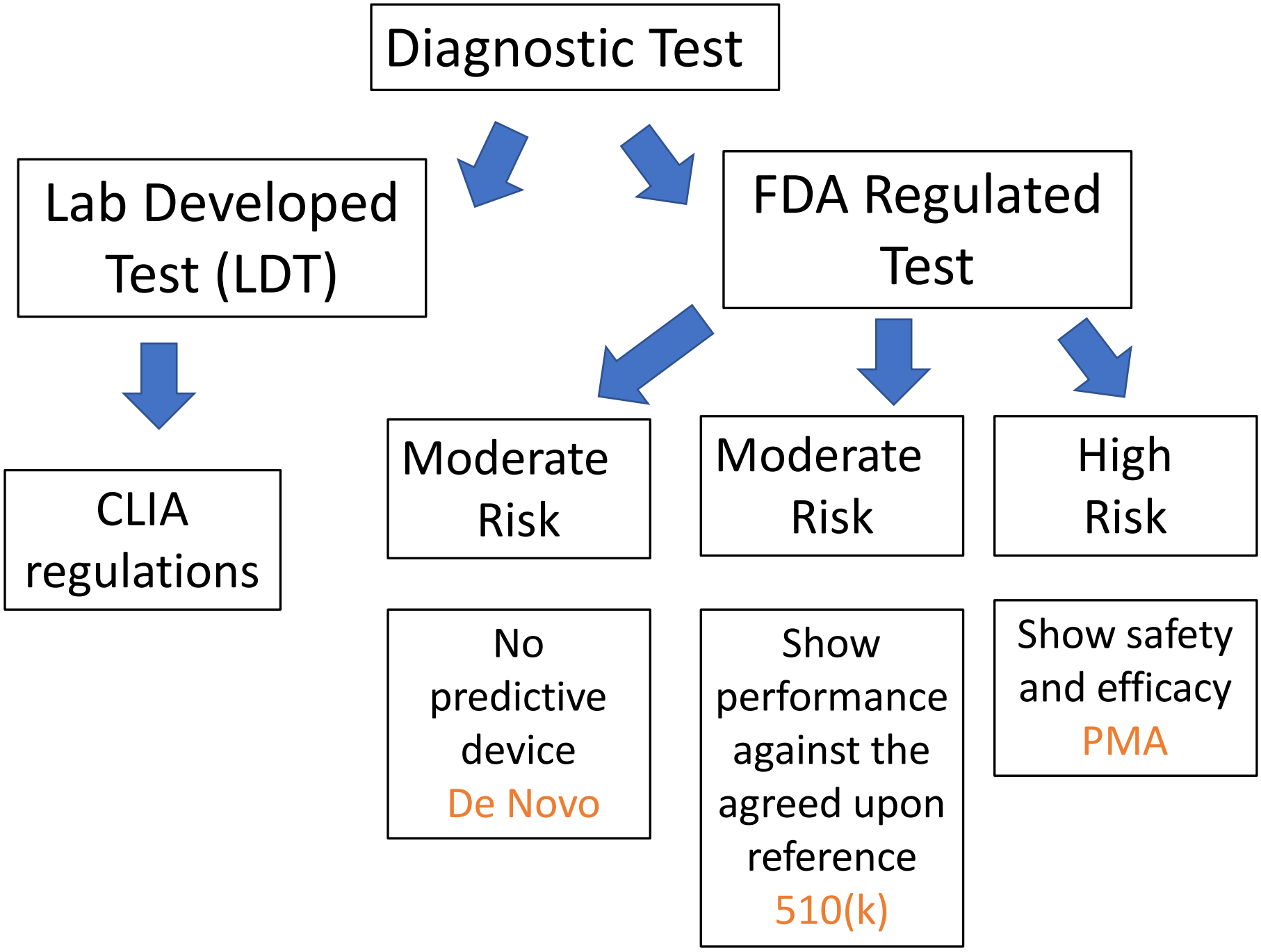
COVID19 and Understanding the FDA Process

Emergency Use Authorization

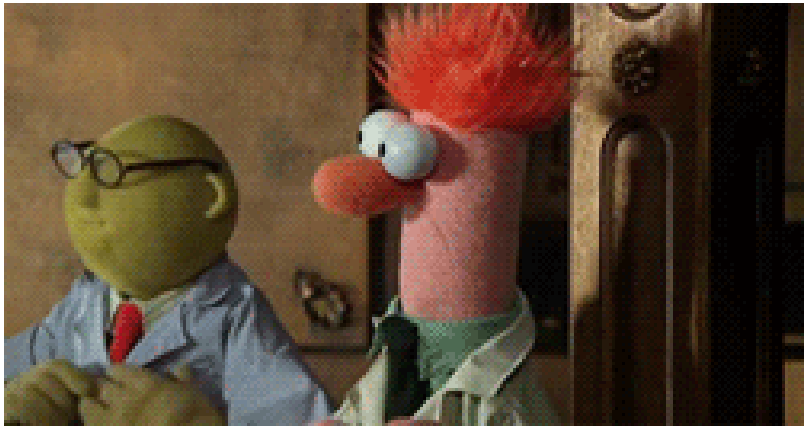
- EUA vs 510k
- The basic workflow of an EUA:
  - Emergency Declaration
  - CMS contacted and must agree to a verification scheme
  - FDA approves the assay based upon a stringent set of criteria that have been agreed upon with CMS
  - EUA is released and labs may begin testing upon verification at the minimum level listed in the insert instructions
  - Emergency order is lifted and all testing under the EUA ceases

The FDA 510k

- Premarket submission to demonstrate that product is safe and effective
  - De novo
  - Traditional
  - (PMA)
- There are multiple classes of devices for human use
- FDA has a goal of 90 days to make a decision


Diagnostic Test
Lab Developed Test (LDT)
FDA Regulated Test
CLIA regulations
Moderate Risk
Moderate Risk
High Risk
No predictive device
De Novo
Show performance against the agreed upon reference
510(k)
Show safety and efficacy
PMA

What's up with CDC removing an EUA they had for a COVID test?



COVID Tests CDC

- Single-plex (COVID only)
- This is being removed from EUA
  - Expensive to run by itself when also wanting flu data
  - Doesn’t make sense to offer to labs when there are so many other high throughput options now
  - Common for a site to remove an EUA to move to another test type though this does make it look like a test recall
- Multi-plex (COVID and Flu)
- Still offered and is comparable to the single-plex was, but adds one more result to the test

The final word…

- Not all EUA recalls are the same….
- A voluntary recall to push for another test is generally a financial decision and not an issue with test sensitivity/specificity issue
- A FDA revoked EUA generally refers to a test being forcefully pulled from market due to testing concerns of some sort

QUESTIONS?


LOST
CONFUSED
UNSURE
UNCLEAR
PERPLEXED
DISORIENTED
BEWILDERED

Concluding Remarks

Reminder

A recording of today's presentation will be sent to the groups below, and they will email it to their members.

- Community Mental Health Association of Michigan
- Michigan Assisted Living Association
- Michigan Center for Assisted Living
- Leading Age of Michigan

You can also download the slides from our presentations at Michigan.gov/Coronavirus. Click the RESOURCES tab and select "For AFC and HFA Operators." Scroll to bottom of page.

Questions on other topics can be sent to:

Staffing: MDHHS-LTCStaffing@michigan.gov

Vaccines: MDHHS-COVID-Longtermcare@Michigan.gov

Testing: MDHHS-COVIDTestingSupport@michigan.gov

Emergency Orders: MDHHS-MSA-COVID19@michigan.gov

All Other Questions:
MDHHS-COVID-AFC-HFA-Response@michigan.gov

- Subscribe to correspondence at this link: Subscribe