

Newborn Screening: Current Status of State Newborn Screening Programs

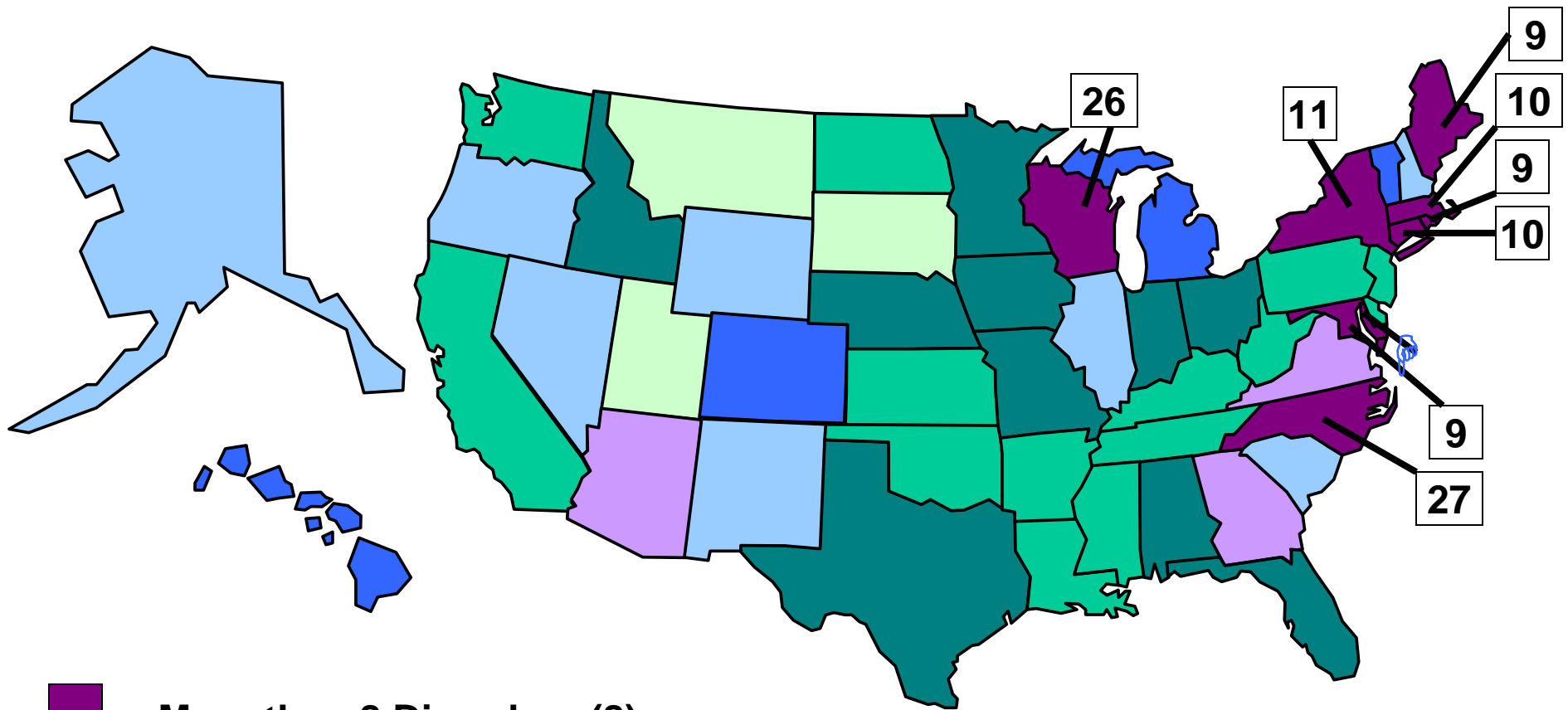
October 20, 2005

Brad Therrell, Ph.D.

University of Texas Health Science Center at San Antonio

Newborn Screening and Genetics Resource Center

Austin, Texas



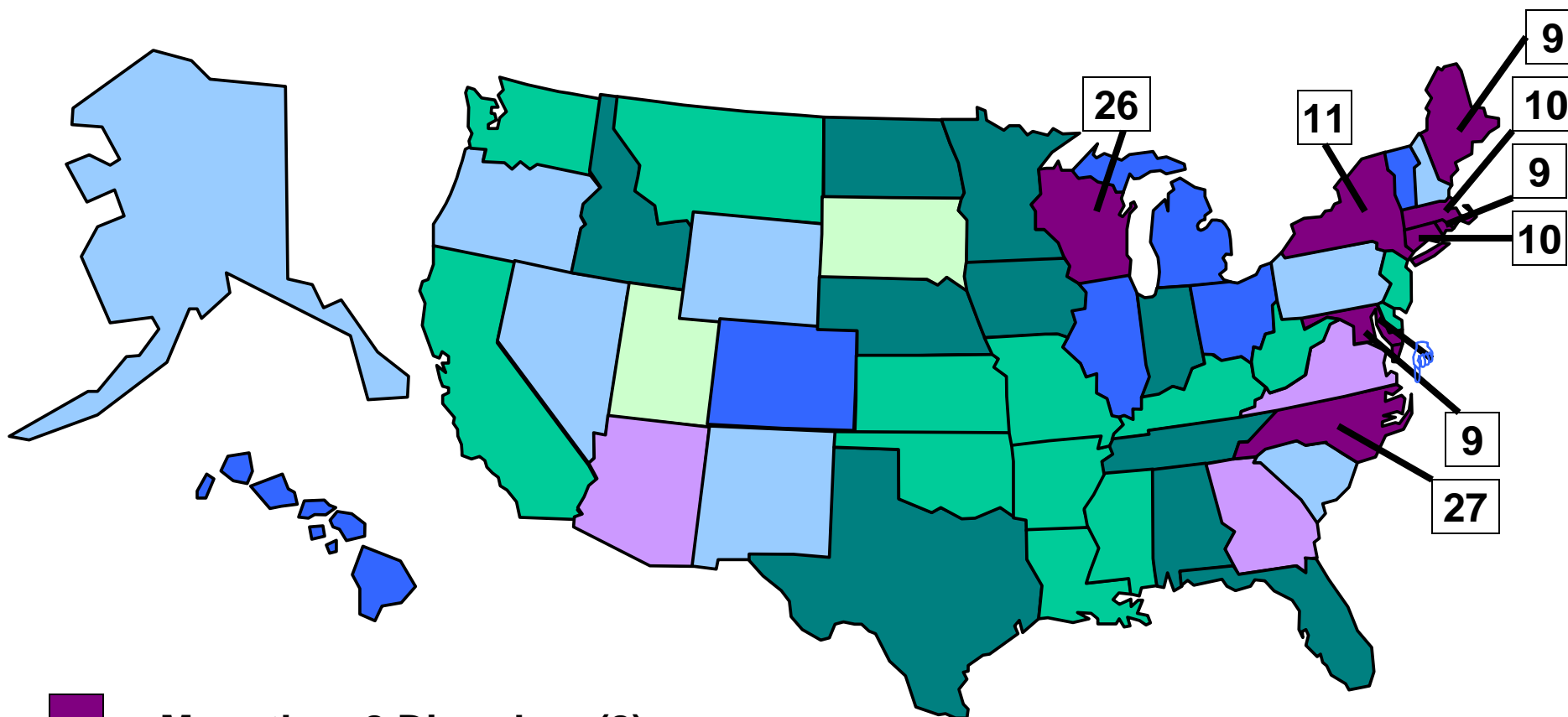
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U.S. Newborn Screening

Mandated Disorders – October 2000
(Note: Other disorders may be offered but are not mandated)

(Note: Hemoglobinopathy screening counts as 1 screening disorder.)





- More than 8 Disorders (8)
- 8 Disorders (3)
- 7 Disorders (7)
- 6 Disorders (8)
- 5 Disorders (10)
- 4 Disorders (13)
- 3 Disorders (2)

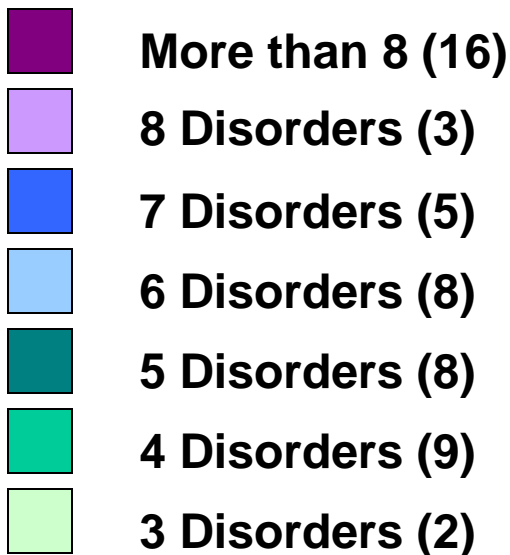
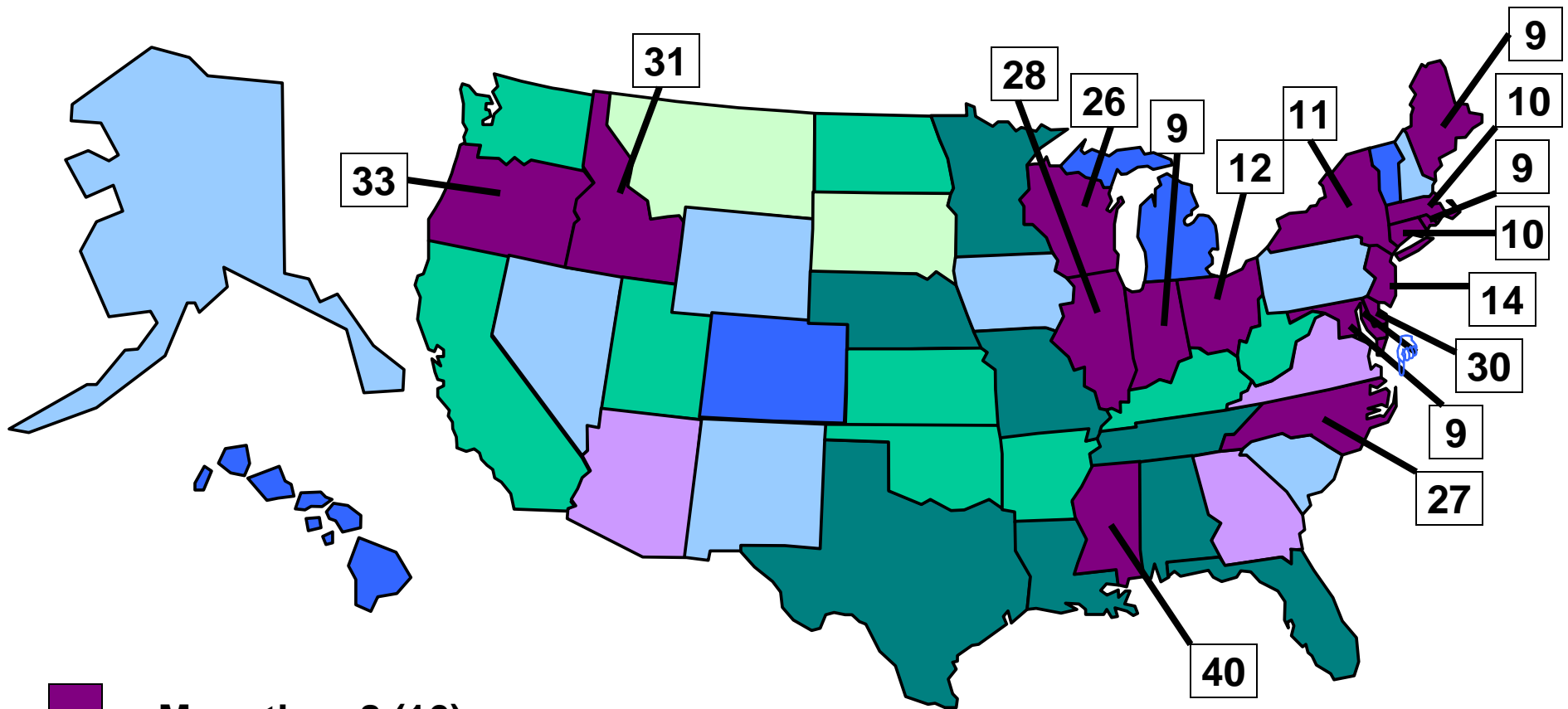
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U.S. Newborn Screening

**Mandated Disorders – May 2001 (Note:
Other disorders may be offered but are
not mandated)**

(Note: Hemoglobinopathy screening counts as 1 screening disorder.)



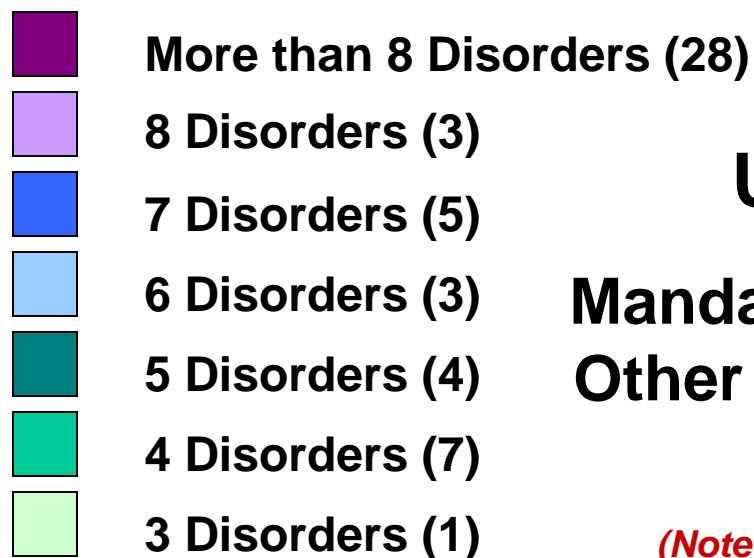
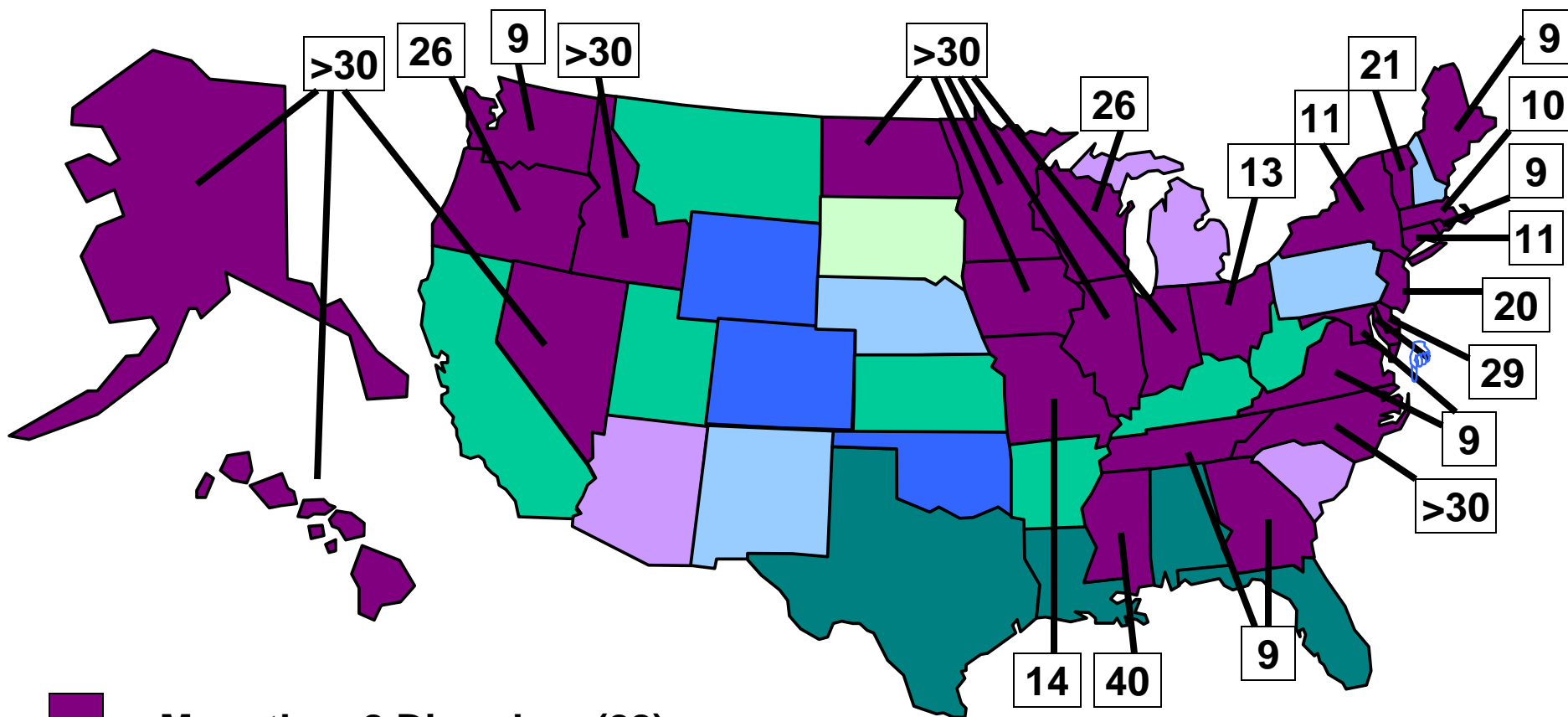


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U.S. Newborn Screening

Mandated Disorders – March 2003
 (Note: Other disorders may be offered but are not mandated)

(Note: Hemoglobinopathy screening counts as 1 screening disorder.)

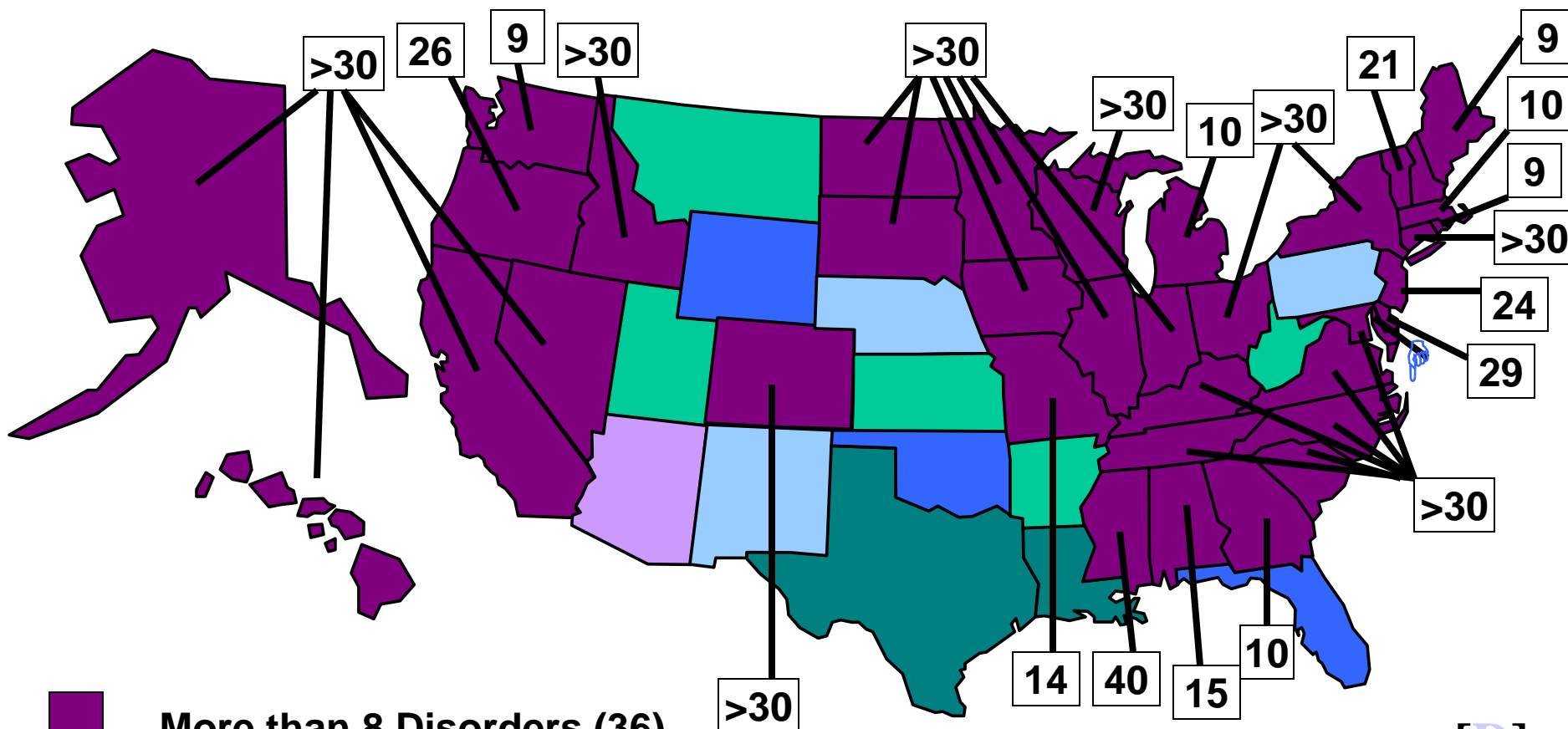


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U.S. Newborn Screening

Mandated Disorders – May 2004 (Note: Other disorders may be offered but are not mandated)

(Note: Hemoglobinopathy screening counts as 1 screening disorder.)



- More than 8 Disorders (36)
- 8 Disorders (1)
- 7 Disorders (4)
- 6 Disorders (3)
- 5 Disorders (2)
- 4 Disorders (5)
- 3 Disorders (0)

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U.S. Newborn Screening

Mandated Disorders – October 2005
 (Note: Other disorders may be offered but are not mandated)

(Note: Hemoglobinopathy screening counts as 1 screening disorder.)





Alaska



- CPT - I Cases: Currently 22 detected (all Native Alaskans)
 - Significance as yet undetermined – Began screening Oct. 2003 [about 10,000 annual births (25% Native Alaskans)]
 - ~1:225 Native Alaskan Births
- Newborn Screening Advisory Committee created CF Task Force to consider issues related to adding CF screening.



Colorado



- Completed NNSGRC Program Review
- Currently planning implementation - Spring 2006



Florida



- October 1 – Began biotinidase screening statewide



Iowa



- July 18 – Began CF screening
- September 8 – Began receiving Louisiana NBS specimens
- Has temporary staff in place to maintain testing for several months
- Participating in national public service project to retest LA babies for which testing is unsure.



Maine



- September – NBS Advisory Committee recommended including the 19 optional tests currently offered as part of the required screening panel.
- January 1, 2006 – Required tests go from 9 to 28.



Mississippi



- Hurricane Katrina – No significant outfall – Specimens tested out-of-state at Pediatrix – Courier for transport
- Contractor and State pursuing any possible missed screens and lost reports



New Jersey



- September - Newborn Screening Annual Review Committee (NSARC) – Recommendations to Commissioner:
 - Computer system upgrade
 - Upgrading training of current lab personnel
 - Hiring better trained lab personnel
- Reviewing parent and professional literature as outfall from the ACMG Report.



Pennsylvania



- SB 901, Oct. 5, 2015 – Further defines “disease” by adding testing for severe combined immunodeficiency -
“Diseases listed by the Department ..., and severe combined immunodeficiency (SCID).”



Rhode Island



- Preparing for Regulatory Hearing prior to expand to ACMG recommended core panel.
- Expansion to 29 core disorders anticipated July 2006 (currently only MCAD and amino acids)



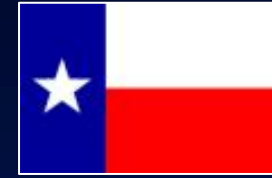
South Carolina



- Initiated expanded data reporting system
- Long-term goal is Internet Access by primary care providers



Texas



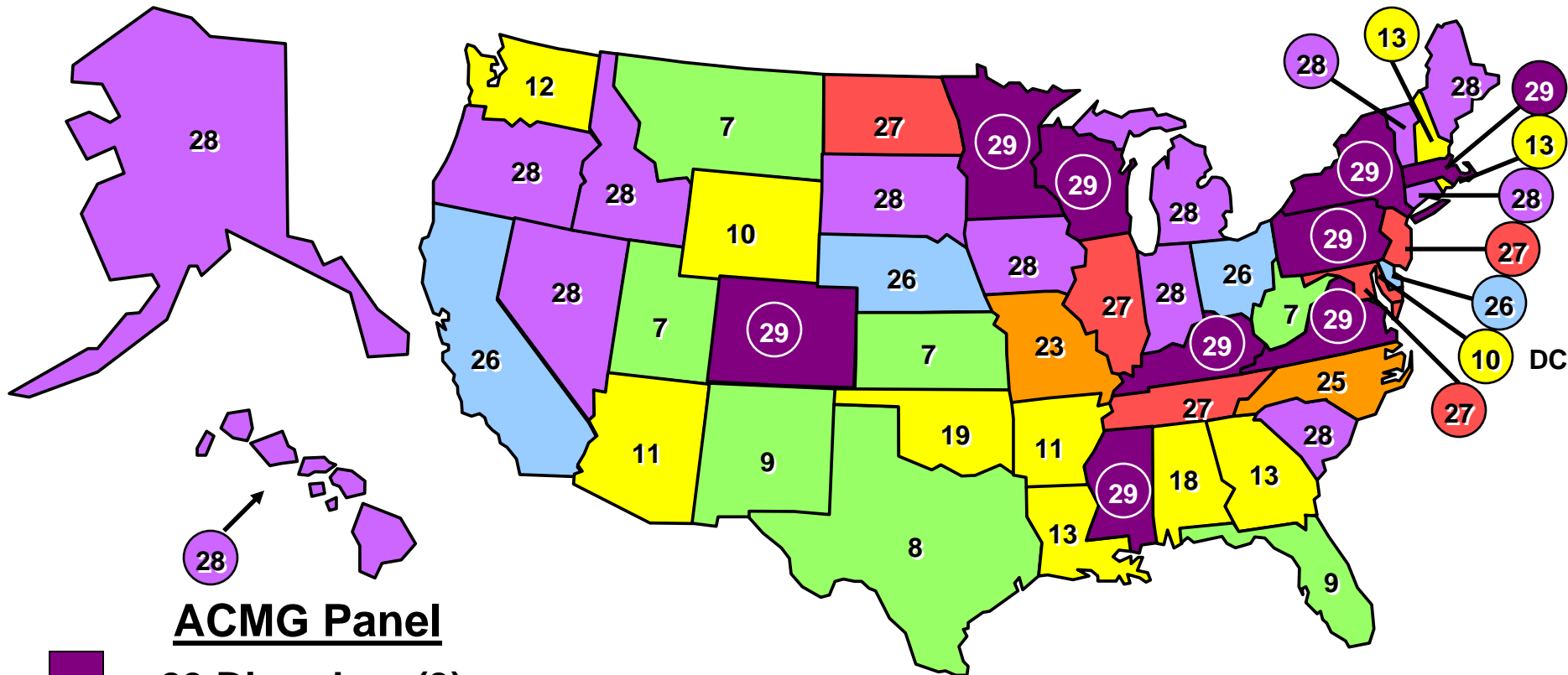
- Partner meetings to address issues to be included in potential RFP – Must be 10% lower than in-house cost for acceptance
- Must respond to NNSGRC Review and perform cost analysis (March 2006)
- Anticipated start of expanded testing – Oct. 2006



Washington



- October 17, 2005 – Board of Health gave approval to file rule to add CF and to begin process of evaluating 16 conditions for inclusion in screening panel – remainder of “ACMG 29”
- February 2006 – Projected date for finalizing addition of CF.



ACMG Panel

- 29 Disorders (9)
- 28 Disorders (13)
- 27 Disorders (5)
- 26 Disorders (4)
- 23-25 Disorders (2)
- 10-19 Disorders (11)
- <10 Disorders (7)

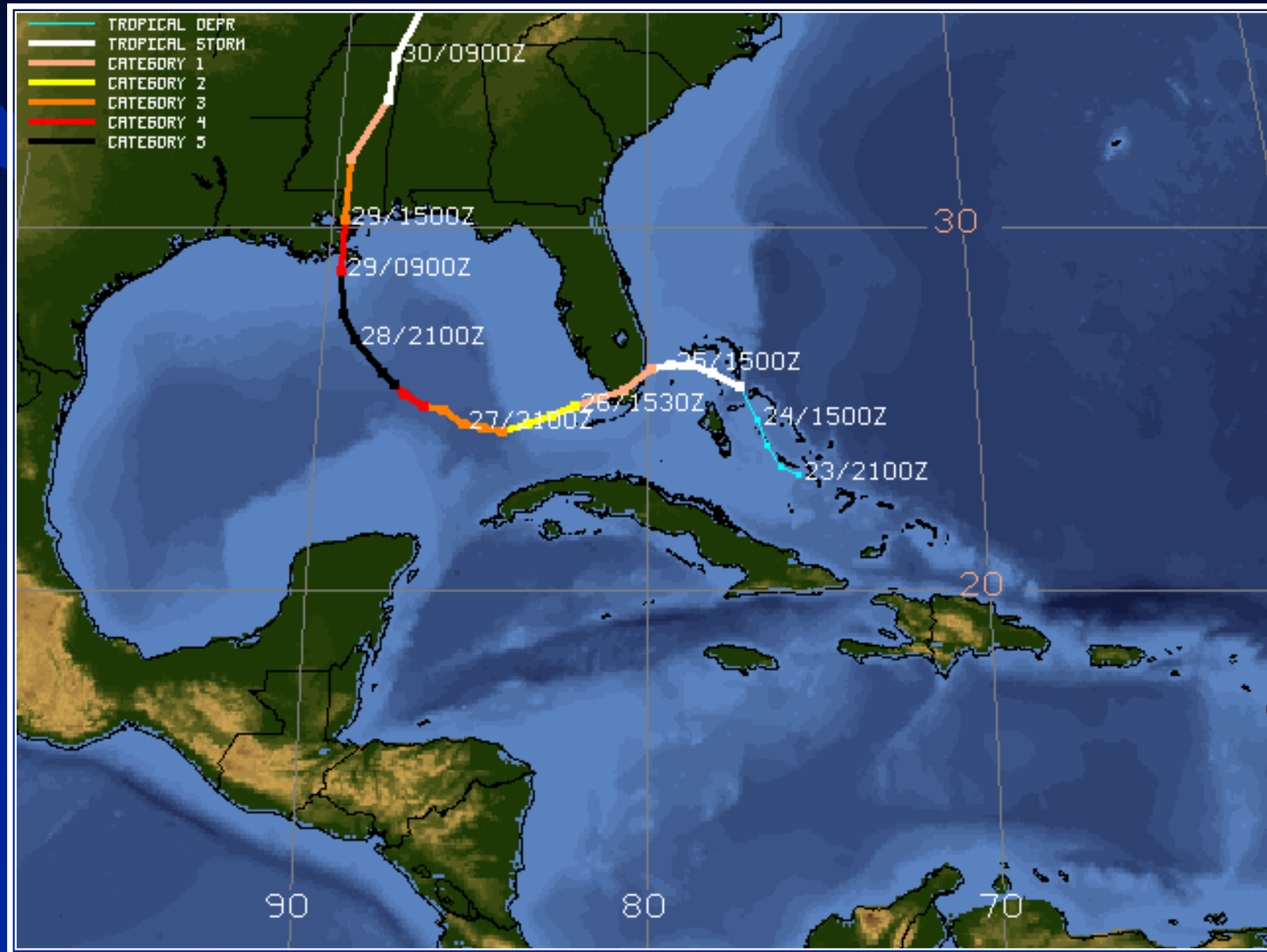
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U.S. Newborn Screening

Conditions Required or Universally Offered – October 2005

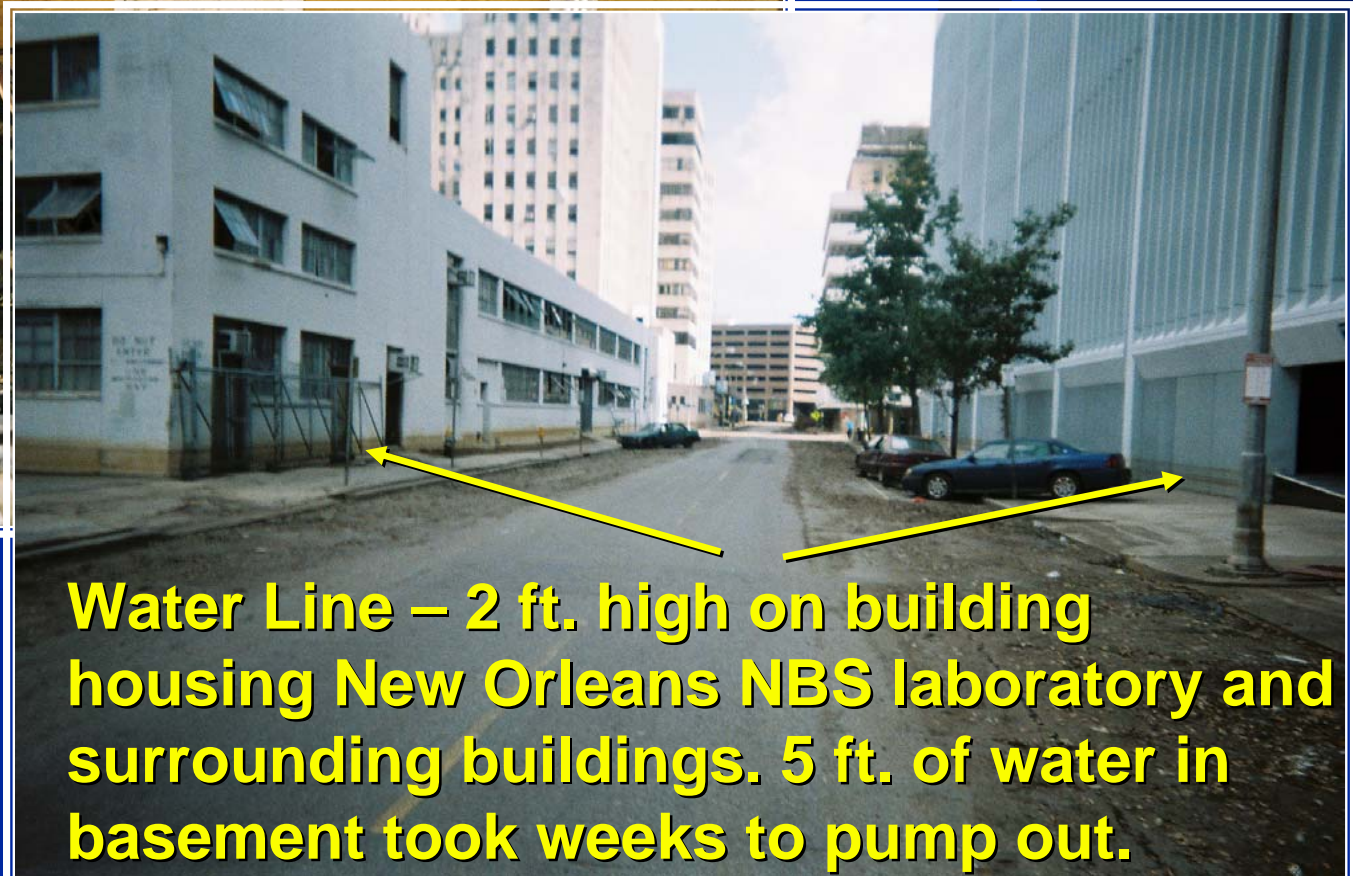
(Conditions available as an option to selected population are not counted)

Hurricane Katrina – Louisiana/Mississippi



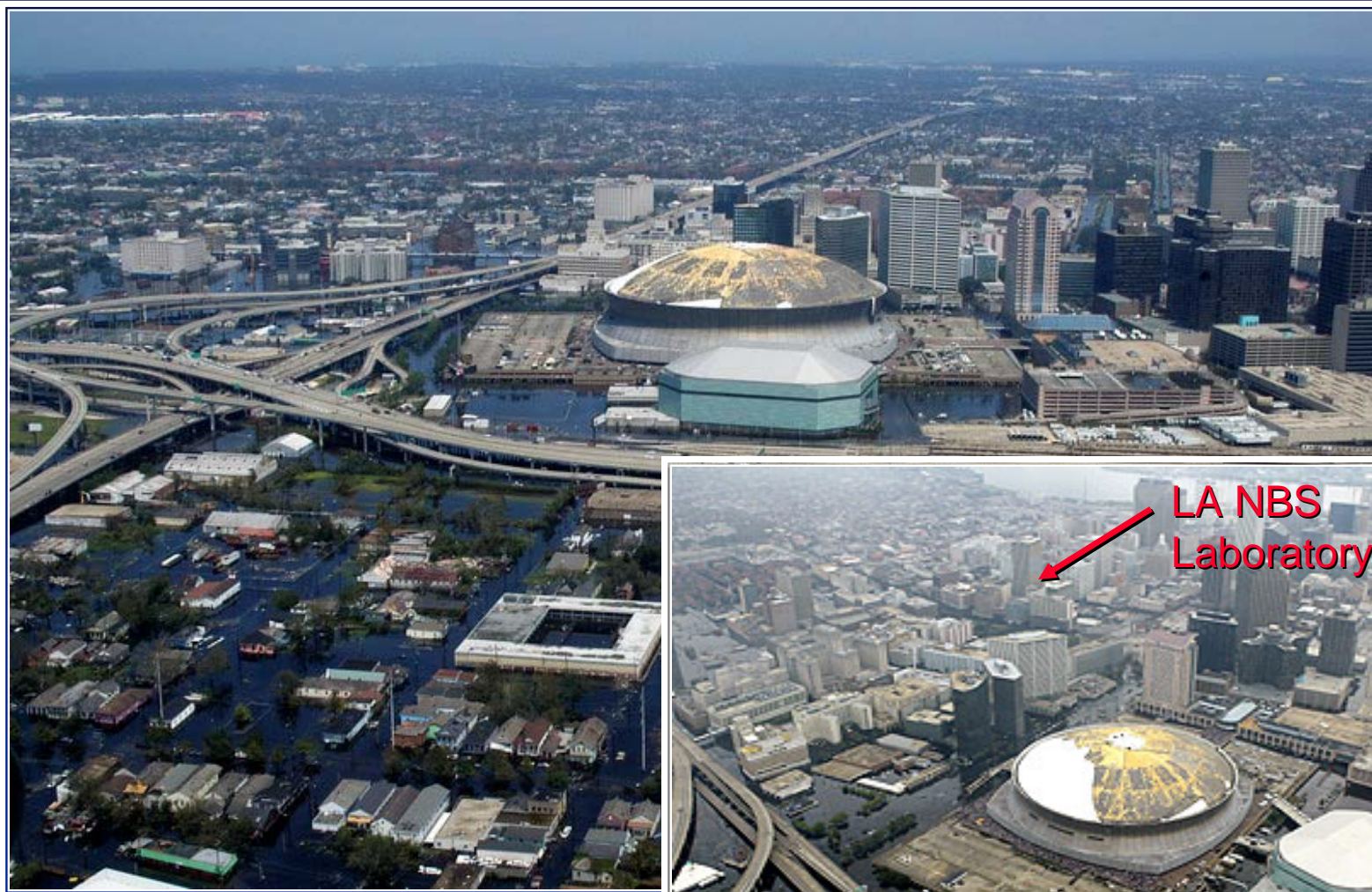
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Hurricane Katrina – New Orleans, Louisiana



Water Line – 2 ft. high on building housing New Orleans NBS laboratory and surrounding buildings. 5 ft. of water in basement took weeks to pump out.

Hurricane Katrina – New Orleans, Louisiana



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Newborn Screening – Katrina



Timeline

August 29	Katrina hits New Orleans
August 31	Louisiana NBS seeks help
September 1	EMAC, “Interstate Mutual Aid Request” from Louisiana
September 2	Iowa software demonstrated on Web EMAC offer from Iowa signed
September 3-5	<i>Labor Day weekend</i>
September 6	Iowa given NBS mission
September 8	Iowa receives first samples



Newborn Screening – Katrina



[<http://www.emacweb.org>]

- EMAC, the Emergency Management Assistance Compact, is a congressionally ratified organization that provides form and structure to interstate mutual aid.
- Through EMAC, a disaster impacted state can request and receive assistance from other member states quickly and efficiently, resolving two key issues upfront: liability and reimbursement.
- EMAC is administered by the National Emergency Management Association (NEMA) [<http://www.nemaweb.org>]



Newborn Screening – Katrina



Operational Issues

- Merging state systems
 - Test menu
 - Specimen timing
 - Data collection
 - Data reporting
 - Follow-up



Newborn Screening – Katrina



Operational Issues

- Increased testing capacity
 - Test
 - New facility – adequate space – occupied 3 months
 - Redeploy, hire technical and data entry staff
 - MS-MS devices – two available
 - Punch devices – additional punch provided by Perkin Elmer
 - Reagents - Perkin Elmer
 - Data entry
 - Scan collection card into information system
 - Remote data entry with side-by-side system
 - Patient demographics on left entered into web entry form on right
 - Even the Director entered data the first week



Newborn Screening – Katrina



**Dr. Mary Gilchrist, Iowa Public Health Laboratory Director
Assisting in data entry for Louisiana NBS specimens**

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Screening Louisiana Newborns in Iowa

Implementation Issues

- APHL facilitated linking activities
- Multiple offers for assistance including private screening providers and reagent/instrument manufacturers
- EMAC used for public health emergency response
- Major issues: Screening panel - Reporting
- Confirmatory laboratories – Miami (Gal), Maryland (PKU), D.C. (other metabolics)
- One month of screening (9/8-10/7)
 - Reported results on 4,923 newborns
 - Reported out 35 presumptive positives – 1 diagnosed PKU

Screening Louisiana Newborns in Iowa

Other Issues

- Payment for screening activities not yet resolved – assumption is that EMAC will assist – reagents donated for 3 month period
- Pharmacy for distribution of metabolic formula – relocated from New Orleans to another city – payment issues to be resolved (procurement rules, etc.)
- Follow-up staff – 1 temporarily hosed in Mississippi DOH, others in Baton Rouge
- Hospitals slowly reopening – some specimens held, some lost, patients displaced
- Ongoing effort to locate unscreened newborns – CDC, LA DOH, IA DOH, PSAs, toll-free call in available