



# Update on SACHDNC Administrative Processes

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Committee on Heritable Disorders in Newborns and  
Children**  
**Department of Health and Human Services**  
**Health Resources and Services Administration**  
**Maternal and Child Health Bureau**



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## Updates

- 2013 Newborn Screening Saves Lives Act re-authorization
  - So far no action has been taken
  - Does not “sunset” so if funds are appropriated, programs can continue
- 2012 Annual Report
  - Reviewed and approved by AC
  - Sent to Secretary Sebelius

# Organizational Representatives

- Nominations may be considered upon written requests to the DFO from individuals, organizations or the Committee. Requests should document the following:
  - perspective and expertise provided by the nominated representative
  - why this perspective and expertise would benefit the Committee
  - how the SACHDNC's work affects and/or impacts the nominated representative's organization and stakeholders
  - commitment of the nominated representative to provide expert input into the SACHDNC decision-making process,
  - source of funding for travel and per diem support, and
  - means of ensuring active dissemination to their representative constituencies about SACHDNC activities and recommendations.
- Nominations will be reviewed by the Chair and DFO prior to submission for Secretarial selection.



# Organizational Representatives on SACHDNC



## SACHDNC Organization Representatives - Categories and Rotations

Category	# of Reps	Org Name	New Term Begins
Federal Agencies	Up to 1	Department of Defense	Jan 2016
Public Health Constituencies - State and Local - includes hospitals and medical home	Up to 2	Association of Public Health Laboratories	Jan 2013
		Association of State and Territorial Health Officials	Jan 2016
Consumer/family organizations, advocacy groups	Up to 2	Genetic Alliance	Jan 2014
		March of Dimes	Jan 2015
Primary Care - includes nursing	Up to 3	American Academy of Family Physicians	Jan 2014
		American Academy of Pediatrics	Jan 2016
		American College of Obstetricians and Gynecologists	Jan 2015
Subspecialty	Up to 2	Society for Inherited Metabolic Disorders	Jan 2015
		American College of Medical Genetics	Jan 2014
At Large Reps	Up to 2	Child Neurology Society	Jan 2013
		<b>Vacant</b>	



# Subcommittee Discussion

For reports and projects sent  
forward for AC review



# What Nature of Support is being requested?



NATURE OF SUPPORT	RECOMMENDATIONS AND/OR ACTIONS
Official SACHDNC Support	Products or Projects are FORWARDED TO SECRETARY FOR CONSIDERATION/ACTION - in purview of SACHDNC and under authority of HHS Secretary
SACHDNC Affirmation of Value to the Heritable Disorders and Newborn Screening Community	Products or Projects are FORWARDED TO SECRETARY FOR INFORMATION PURPOSES ONLY
SACHDNC Acknowledgment	Products or Projects are <u>NOT</u> FORWARDED TO THE SECRETARY. ACKNOWLEDGMENT CITED ON SACHDNC WEBSITE
No Support	N/A



## Official SACHDNC Support with Actions:

1. What action(s) and/or recommendations is/are being requested?
2. Please list the pros and cons of each action and/or recommendation
3. What is the best mechanism for the Secretary to support these actions and/or recommendations?



## Template for voting slide:

- Report title
- Nature of support requested
- ***If official support with actions***
  - List of actions/recommendations
  - Pros and cons of each action/recommendation
- How can the Secretary best support these actions and/or recommendations for optimal outcomes?

# Condition Nomination Forms

- Addition of a Pre-nomination requirement:
  - Comment: For a condition to be sent to the condition review group there are 3 core requirements:
    - 1. A prospective population based pilot
    - 2. Validation of the laboratory test
    - 3. Widely available confirmatory testing with a sensitive and specific diagnostic test



<b>PreNomination Preparation</b>	Comment: For a condition to be sent to the condition review group there are 3 core requirements: 1. A prospective population based pilot 2. Validation of the laboratory test 3. Widely available confirmatory testing with a sensitive and specific diagnostic test			
<b>Population Based Pilot</b>	Location of prospective pilot	Number of infants screened	Number of screen positive results	Number of infants confirmed with diagnosis
<b>Laboratory Test Validation (as applicable)</b>	Analytical Sensitivity	Analytical Specificity	Reportable Range of Test results	Reference Range
<b>Confirmatory testing</b>	Type of test (blood, radiology, urine, tissue sample, biophysical test)	Is test FDA and/or CLIA certified? (Y/N)		Offered routinely at >2 CLIA certified labs in the US and where?



# Contact Information

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