



Request for Proposals (RFP): Support for Newborn Screening Implementation of New RUSP Disorders

Letter of Intent Due Date: September 5, 2017 by 5:00 pm ET

Application Due Date: October 13, 2017 by 5:00 pm ET

Technical Assistance Webinar: September 15, 2017 at 2:00 pm ET

Submit to: Kshea Hale, NewSTEPS (kshea.hale@aphl.org)

The development of this request for proposals application was supported by Cooperative Agreement Number UG9MC30369 from the Health Resources and Services Administration (HRSA). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of HRSA.

Please send completed application to Kshea Hale, kshea.hale@aphl.org, 240.485.3842 by October 13, 2017.

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SUMMARY

The Association of Public Health Laboratories (APHL) is looking to identify up to five state newborn screening (NBS) programs to implement NBS for one or more of the following disorders: Pompe, Mucopolysaccharidosis Type I (MPS I) and X-linked Adrenoleukodystrophy (X-ALD) (described in more detail in the [Background](#) section below). APHL uses the term “New Disorders” in this RFP to refer collectively to these three disorders.

APHL anticipates that each subawardee would receive up to \$70,000 for one year for implementing new disorder screening.

BACKGROUND

Public health programs in the US screen approximately 4 million newborns for at least 26 conditions every year. While the Health and Human Services (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) recommends conditions to be included on the Recommended Uniform Screening Panel (RUSP), each state determines the specific conditions for which it screens. To be effective and successful, the NBS system requires the capability to detect conditions accurately, to provide education and training, and to refer newborns for treatment upon identification of condition.

Pompe newborn screening was added to the RUSP in March 2015 and X-linked Adrenoleukodystrophy (X-ALD) and Mucopolysaccharidosis I (MPS I) were added in February 2016. As of August 1, 2017, seven states are screening for Pompe, six states are screening for MPS I, and five states are screening for X-ALD. Details regarding states’ implementation of RUSP conditions are available at www.newsteps.org.

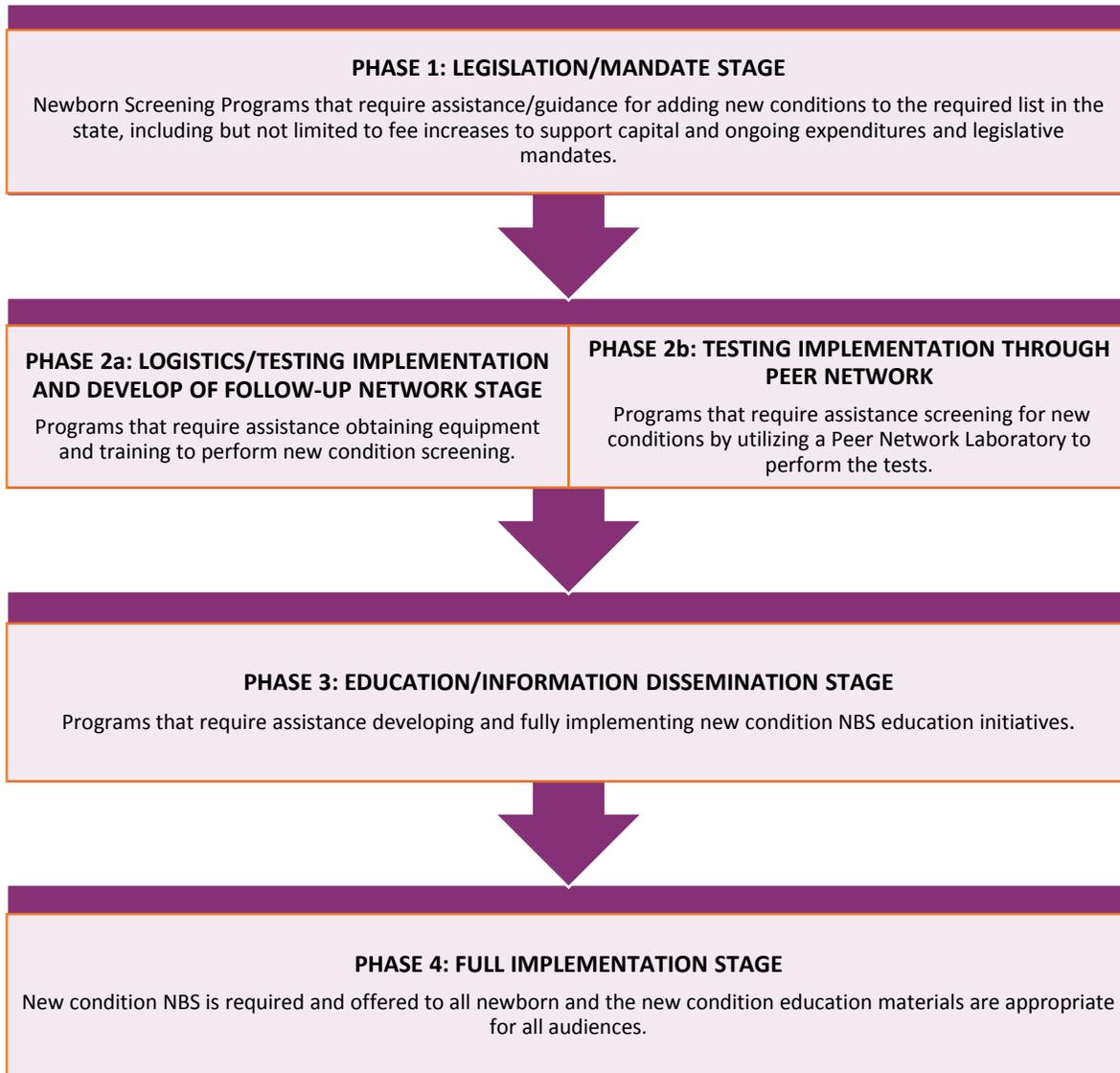
The HHS’s Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau, Genetic Services Branch awarded Cooperative Agreement #UG9MC30369 (the Cooperative Agreement) to APHL in order to enhance, improve or expand the ability of state and local public health agencies to screen for the New Disorders as part of their newborn screening program. The Cooperative Agreement also seeks to provide health care professionals and newborn screening laboratory personnel with education and training in newborn screening for the New Disorders, and support the development and dissemination of appropriate education and training materials. APHL’s collaborative partnership with the Colorado School of Public Health, Baby’s First Test and the Newborn Screening Translational Research Network supports the goals of the Cooperative Agreement and provides resources, education and training materials related to the New Disorders. The activities under this Cooperative Agreement are being performed in close collaboration with NewSTEPS, a program of APHL in collaboration with the Colorado School of Public Health, which is funded under Cooperative Agreement #U22MC24078 from HRSA.

The key deliverables of the Cooperative Agreement include moving states who have not yet fully implemented newborn screening for Pompe, MPS I and/or X-ALD closer to full implementation. For many programs this will result in statewide mandates that newborns receive Pompe, MPS I and/or X-ALD screening and all laboratory, follow-up and educational components are in place for full implementation. Other states may still need to get Pompe, MPS I and/or X-ALD NBS added to the required list and secure necessary authority for Pompe, MPS I and/or X-ALD NBS. Within a one-year

period these states may not have achieved full implementation, but will be able to demonstrate progress towards this goal. NewSTEPS has developed a four-phased implementation model that demonstrates the new condition NBS stages in which NBS programs currently reside (Figure 1).

To facilitate a network of experts that can assist NBS programs in implementing screening for the conditions, APHL supports Peer Network Resource Centers. These Peer Network Resource Centers serve as content area experts on the laboratory techniques, follow-up procedures, and other new condition related activities. Further, these networks offer first- and/or second-tier testing within their laboratories in order to facilitate screening in other states.

Figure 1: New Condition NBS Implementation Stages Stratified into a Four-Phase Model



RFP PROCESS OVERVIEW

August 24, 2017	–	RFP Issued
September 5, 2017	–	Letter of intent due by 5:00 pm ET to APHL (see the Letter of Intent section below)
September 15, 2017	–	Technical Assistance Webinar at 2:00 pm ET (see NewSTEPS listserv for webinar details)
October 13, 2017	–	RFP responses due by 5:00 pm ET to APHL
November 10, 2017	–	Awardees notified
December 22, 2017	–	Contracts ratified between APHL and awardees

Any modification to this anticipated schedule will be communicated on APHL's procurement website (www.aphl.org/rfp) and via an email blast to the NBS Programs and the public health laboratories.

TECHNICAL ASSISTANCE WEBINAR

Date: Friday, September 15, 2017

Time: 2:00 pm ET

Duration: 1 hour

Dial-In: 866.740.1260 | Access Code: 4852701

Web Login: <https://cc.readytalk.com/r/c4tpnyd4reuz&eom>

PREREQUISITES

1. Applicant must commit that, if accepted, they will be able to sign a contract with the Association of Public Health Laboratories (APHL) for acceptance of funds by **December 22, 2017**.
2. Applicant must be able to participate in monthly webinars for the duration of the award and to one face-to-face technical assistance meeting in spring 2018.
3. Applicants must be willing to provide baseline data for newborn screening for any or all of the three conditions (Pompe, MPS I, X-ALD), including status of legislative mandates, number of newborn screened, current progress on educational activities and status of follow-up programs. This information will be collected at the beginning of the funding period, during routine intervals and at the end to measure progress, and will be outlined in detail during the preliminary webinars for each selected program.

LETTER OF INTENT

APHL requests that prospective applicants submit a brief email statement indicating a firm intent to submit a proposal by no later than the RFP Due Date. Although a letter of intent is not binding, and does not enter into the review of the RFP, the information that it contains allows APHL to estimate the potential review workload and plan the contract development and review process. Potential applicants must include the name of the organization or individual that will submit the proposal in their email.

The prospective applicants should email a statement reflecting the intent to apply to the contact identified in the [Submission of RFP](#) section below using the subject line: LETTER OF INTENT: NEW DISORDERS RFP. APHL must receive this information by **5:00 pm ET on September 5, 2017**.

SUBMISSION OF RFP

Applications must be received at APHL, attention Kshea Hale by close of business (5:00pm ET) October 13, 2017. Either electronic or physical submission is acceptable. APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within 48 hours, call 240.485.3842 to confirm receipt.

Physical applications must be sent to the following address:

Kshea Hale
Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700
Silver Spring, MD, 20910
Telephone: 240.485.3842

Electronic submissions must be sent to Kshea Hale at kshea.hale@aphl.org with a copy to newsteps@aphl.org

OBJECTIVE

The primary focus of this request for proposals is to support newborn screening programs and other entities through technical and financial means in order to achieve both a greater number of states mandating NBS for Pompe, MPS I, and/or X-ALD and a greater number of newborns receiving appropriate screening and follow-up for any or all of the three conditions (Pompe, MPS I, X-ALD).

ELIGIBLE APPLICANTS

All U.S. and territorial NBS programs who have not fully implemented Pompe, MPS I, and/or X-ALD screening (defined as: demonstrated ability to test all newborns for Pompe, MPS I, and/or X-ALD, having a clinical referral network to follow and treat identified newborns, and having an educational and awareness program for families and health care providers).

REQUIREMENTS OF FUNDING REQUESTS

The award money can be used, but is not limited to, the following costs associated with Pompe, MPS I, and/or X-ALD NBS:

- Laboratory equipment
- Pilot testing of Pompe, MPS I, and/or X-ALD NBS procedures
- Meetings and Trainings
- Educational outreach and dissemination

- Costs associated with hosting visitors for technical assistance at any of the first three phases of Pompe, MPS I, and/or X-ALD NBS implementation
- Supporting costs associated with engaging a Peer Network Resource Centers' time for leading educational and screening efforts
- Other targeted activities that will facilitate the implementation of screening for these new disorders

TRAVEL

All awardees will be required to attend an in-person meeting in summer 2018, and two staff members will be covered.

APHL will also support travel for up to 3 staff members to spend one week onsite at a Peer Network Resource lead laboratory or follow-up program for training purposes.

EXPECTED OUTCOMES

These awards will build capacity of states to screen for Pompe, MPS I and/or X-ALD and to perform outreach and education around any or up to all three of the conditions. NewSTEPS will support programs to monitor training, quality improvement activities and screening status through robust tracking mechanisms.

EVALUATION OF RESPONSES

Initial Review

APHL will conduct an initial review of all proposals for completeness. Any application that is incomplete on the RFP Due Date (see [Anticipated RFP Schedule](#) above) will not be considered and will not receive a formal evaluation.

Evaluation Team

After the initial review, an evaluation team will be assembled to evaluate competitive proposals and then assess their relative qualities based on the [Evaluation Criteria](#) outlined below and any other factors and sub-factors noted in this RFP. This evaluation team will consist of at least two Subject Matter Experts (SMEs) familiar with disorder implementation. The SMEs may consist of APHL members or other external individuals that have expertise in the content area. In addition, the review team may include ColoradoSPH or HRSA employees, SMEs with whom APHL or ColoradoSPH has previously worked, or other SMEs referred to APHL by ColoradoSPH, HRSA or one of the association's members. APHL's Senior Director for Public Health Systems will have final approval over the selected review team's composition.

APHL will ask proposed review committee members to disclose any potential conflict of interest and APHL will not place any individual with a conflict of interest on the evaluation team. In the event that a reviewer identifies a conflict of interest (or if APHL staff have reason to believe that a reviewer may not be impartial) after the evaluation team has been assembled, APHL will exclude that reviewer from further participation in the review process and will eliminate that reviewer's completed reviews from the evaluation process.

Evaluation Criteria

Applications will be evaluated based on need for assistance in Pompe, MPS I and/or X-ALD NBS implementation, demonstration of applicant’s ability to achieve stated goals within the time and budget, ability to provide data to measure change, sustainability of activities following funding period, and thoroughness of the response.

Scoring Criteria and Points	
Scoring Criteria	Points
Disorder(s) and Phase Selection	10 points
Goals	50 points
Sustainability Plan	20 points
Budget and Budget Justification	20 points

AWARD

Up to 5 programs, depending on the strength of applications, will be selected. Each selected site will be eligible for an award of up to \$70,000 for one year which will be distributed via a contract administered by APHL.

TERM OF PROJECT

The project term will be from date of contract signing (approximately December 22, 2017) through August 31, 2018. Each selected program would be notified in advance of any modification to the anticipated scope of work in the funding year.

POST-EVALUATION PROCEDURES

The selected applicants will be notified by APHL within ten business days of the completion of the evaluation discussed above and the names of the selected programs will be posted to APHL’s procurement website, www.aphl.org/rfp on the same day. Unsuccessful applicants will receive notification of these results by e-mail or by U.S. mail within 30 days of the date the name of the winning vendor is posted.

All applicants will be entitled to utilize APHL’s RFP Appeals Process to formulate a protest regarding alleged irregularities or improprieties during the procurement process. Specific details of this policy are located on the procurement website.

CONDITIONS OF AWARD ACCEPTANCE

The eligible applicants must be able to contract directly with APHL or have an existing relationship with a third-party organization that can contract directly with APHL on behalf of the applicant.

RFP RELATED QUESTIONS

All questions should be directed to Kshea Hale at kshea.hale@aphl.org. Questions received from interested parties, together with the answers provided by APHL, ColoradoSPH or HRSA staff will be posted to APHL’s procurement website (www.aphl.org/rfp).

DISCLAIMER AND OTHER GENERAL MATTERS

This RFP is neither an agreement nor an offer to enter into an agreement with any respondent. Once evaluation is complete, APHL may choose to enter into a definitive contract with the selected RFP applicant(s).

APHL must ensure that the selected applicant(s) are neither suspended nor debarred from receiving federal funds and that the applicant(s) meet any other funding eligibility requirement imposed by the Cooperative Agreement. APHL's determination of whether the applicant is eligible to receive Cooperative Agreement funding will be definitive and may not be appealed. In the event that APHL determines that the selected applicant(s) is ineligible to receive Cooperative Agreement funding, APHL will nullify the contract or will cease negotiation of contract terms.

Each applicant will bear its own costs associated with or relating to the preparation and submission of its application. These costs and expenses will remain with the applicant, and APHL will not be liable for these or for any other costs or other expenses incurred by the applicant in preparation or submission of its application, regardless of the conduct or outcome of the response period or the selection process.

RESPONSE REQUIREMENTS

Each complete response packet should include:

- Section 1: Disorder(s) and Phase Selection
- Section 2: Goals
- Section 3: Sustainability Plan
- Section 4: Budget and Budget Justification
- Readiness Tool (completed online).

Other sections of this application package include the following tools to be used as reference only but do not need to be submitted for review:

- Appendix B: Sample Goals Table
- Appendix C: Guide/Instructions for New Disorders Readiness Scale

SECTION 1: DISORDER(S) AND PHASE SELECTION

All applicants must complete and submit the **New Disorder Readiness Scale** online by October 13 at 5 pm ET. We require completing this tool for all three disorders. If you have already completed the New Disorder Readiness Scale for the June 2017 New Disorder meeting, please go in and update your responses. To request access to the online Readiness Scale, please contact Kshea Hale via email at kshea.hale@aphl.org.

Disorder Selection:

Which disorder(s) is your program requesting funding to implement? Check all that apply.

- POMPE
- MPS I
- X-ALD

Please complete and submit the questions below for **each condition** you are applying for.

Based on Figure 1 and your answers to the Readiness Tool, what is your program’s current phase for each of the conditions <u>for which your program is applying</u>?			
	Pompe	MPS I	X-ALD
Phase 1			
Phase 2a			
Phase 2b			
Phase 3			
Phase 4			
Based on Figure 1 and the steps you still need to take based on your answers to the Readiness Tool, where do you anticipate your program will be for each of the conditions for which your program is applying after one year of funding?			
	Pompe	MPS I	X-ALD
Phase 1			
Phase 2a			
Phase 2b			
Phase 3			
Phase 4			

SECTION 2: GOALS

Please describe:

- (1) What you are hoping to accomplish with this funding.
- (2) What phase you believe you will be at for each condition you are planning on adding at the end of the funding year.
- (3) What barriers you foresee and your plans to overcome them.
- (4) What support you need outside of the financial support to begin implementing screening for these 3 new conditions.
- (5) What metrics or tools, if any, will your program use to track progress outside the Readiness Tool? As part of this project, NewSTEPS will use the Readiness Tool to measure progress.
- (6) Your team for this project, their expertise, and the role they will play.

In addition to the questions above, please complete and submit the table below for **each** disorder for which you are applying. See Appendix C for a Sample Goal Table for reference.

- o Consider your program goals for New Disorder Screening Implementation over the next twelve months. What steps would you like to complete that are listed in the Readiness Tool?
- o What are the goals over the next year to achieve screen for or get closer to being ready to screen for Pompe, MPS I, and/or X-ALD in your program?
- o List the steps that need to happen, and the approximate start and completion dates for achieving these goals.
- o Make sure application reviewers can easily identify the timing of each activity and the final endpoint for each goal.

New Disorder Screening GOALS TABLE:

GOAL 1					
	Activity	Outcome	Start Date	End Date	Who is lead?
Step 1					
Step 2					
GOAL 2					
	Activity	Outcome	Start Date	End Date	Who is lead?
Step 1					
Step 2					

Add extra lines as needed for additional steps and goal

SECTION 3: SUSTAINABILITY OF NBS ACTIVITIES

All State NBS Programs must complete this question on sustainability of Pompe, MPS I, and/or X-ALD NBS activities

1. How will you sustain Pompe, MPS I and/or X-ALD screening activities (staff, ongoing training, equipment costs and maintenance, consultant contracts, etc.) following the funding period?
 - Fee Change
 - Support from general funds
 - Funding support included in legislative language
 - Other (specify)

2. Please describe the steps involved to implement your sustainability plan, including the time required to implement steps to achieve sustainability, required regulatory approvals and other steps needed to gain approval for sustainability plan.

SECTION 4: BUDGET

BUDGET: A budget should be presented for completion of activities proposed. The budget should include information detailed in the “Requirements of Funding Request” section above.

Budget Template:

Personnel						TOTALS
Name	Position Title	%	Hours per Week	Salary or Stipend	Fringe Benefits	
Equipment (Itemize)						
Supplies/Educational tools (Itemize by category)						
Other Expenses						
TOTAL COSTS						

Budget Justification: Please provide explanation for costs in each category. For personnel please describe staff duties to be covered and experience of staff member.

Personnel:

Equipment:

Supplies:

Other Expenses: