Congenital and Inherited Disorders Advisory Committee
Minutes
February 16, 2018
12:00 p.m. to 2:00 p.m.
Conference Call/ Webinar

M i n u t e s

Members Present	Members Absent	Others Present
Sandra Daack-Hirsch	George Wehby	Kimberly Noble Piper
Bobbi Buckner Bentz	Tom Scholz	Carol Johnson
Val Sheffield	Stewart Boulis	Melody Hobert-Mellecker
Stanton Berberich	Lori Murphy-Stokes	John Bernat
Stacy Frelund	Nate Noble	Seth Perlman
Kimberly VonAhsen	Kelly Schulte	Amy Calhoun
Beth Tarini		
Amanda Devereaux		
Val Sheffield		
Carrie Bernat		
Christina Trout for Hannah Bombei		
Andrea Greiner		
Francis Degnin		
Dan Rowley		
Paul Romitti	Representative Wessel Kroeschell	
	Senator Ragan	

Topics	Discussion/Action
Call to Order	▪ Buckner-Bentz called the meeting to order at 12:05 pm. ▪ Roll call attendance was taken. A quorum is present.
Budget Proposals - Introduction	Piper – The Iowa Newborn Screening Program (INSP) proposed three-year budget is being presented today for discussion and questions. CIDAC will be voting on approval of the budget at the April 20 in-person meeting. While these are three-year budgets, they do not include any costs for the addition of new conditions to the INSP screening panel. Any time a new budget is approved that changes the screening fee, it requires amending of the Iowa Administrative Code 641 IAC 4, because the screening fee is established in code. The administrative rule amendment process takes at least 6 months, and requires State Board of Health approval and a presentation to the Legislative Administrative Rule Review Committee (LARRC). Because of the rule making process, and the work required of birthing hospitals and providers to update their billing systems and coding to collect the new fee, we always try to provide a multi-year budget.
Budget Proposals - STFU	STFU – asking for an additional RN for follow-up – increased workload; increased caseloads with NICU protocol; time to manage cases through new databases. Also need to add rent for STFU space. Daack-Hirsch ? RN added to STFU for data base use? Carol – using two new databases – all STFU will be using two databases now. Romitti ? – Description of databases OZ and SHL – Carol described differences in data systems.

Budget Proposals - SHL	SHL – Able to share some costs with ND, SD to help keep IA costs down. 60% costs for IA, 20% and 20% for ND and SD. Fixed costs vs incremental explained. Starts with a cost-based budget and builds from there. Budget includes anticipated increases in costs added to base expenses. Looking at about a $5.00 increase in fee for SHL. Three additions to the budget going forward: 1.) As technology and knowledge has advanced, in order to assure the algorithms used to determine risk of conditions are as precise as they can be, there is a need to migrate from population risk analysis to individual risk analysis. This requires an ongoing risk evaluation. Need for bio-informaticist to conduct ongoing analysis. 2.) Second-tier testing will increase due to types of conditions now screened for. 3.) Due to complexity and methods advances, it is no longer realistic to expect all of the laboratorians to be cross-trained in all testing methods. Changing to a team concept where teams are responsible for testing using specific methods. In order to staff these teams, need three additional lab staff. For IT, move to HL7 will require additional expertise. ? Buckner Bentz – How much of the budget comes from fees versus appropriation? Berberich – cost based fee. All costs are covered by fees. No appropriation for any NBS programming. There is an additional 10% of the fee that goes to a developmental fund. This fund supports to advance NBS programming. Courier is included in costs, as well. Metabolic Food Formula fund provides $4.00 from the fee. $1 goes to provide for storage of specimens $2 goes to IDPH to support program administration. Discussion of how hospital/patient is billed. Only appropriation for Food and Formula was eliminated this year. Berberich – multi-year budgeting has allowed the fee to remain stagnant for over 5 years. If we were able to provide the current services going forward, we would still need a fee increase of $5. Additional $15 increase needed to provide the additional services listed above. Fee increases from $122 to $137. Potential to add NBS testing for Alaska. This would reduce the IA cost load to 51%. So even with the additional functions needed for IA, adding the 11,000 AK specimens (revenue), we can absorb IA's share of the costs. Tarini? AK screen the same conditions? Berberich – they screen for an additional condition homozygous in 80% of the population. Costs will be specifically assigned to AK. Degnin – When will we know about AK? AK would like to start July 1, and SHL is working toward this date. CPT1A mutation analysis development is underway. With the addition of new conditions, the Ankeny lab will run out of space to house all of the new instruments. The SHL is actively looking at options. Fee increase will be from $122-$133 if AK. $122 - $137 if no AK.
Budget Proposal – Food and Formula	Sheffield proposing a $6.00 increase to Food & Formula (F&F) allocation. Currently $4. Lost $159,935 state appropriation last year. Ran a deficit of $80,000 which is picked up by the Department of Peds. Budgeting lost appropriation + deficit = $240,000/40,000 births comes to $6/birth. Currently running a larger deficit for the current fiscal year. Deficit comes from no or low reimbursement from insurance. What isn't reimbursed is written off through IowaCares program. Hospital is obligated to write it off. Department of Peds buys the formula and "sells" to patients (cheaper to purchase through hospital purchasing). Sheffield gives history of food and formula budget requests. Stated to IDPH years ago that we should quit doing NBS, if we can't treat. What if question comes up about why we don't pay for ERT, etc.? Calhoun – usually other treatments are covered by

	insurance. F&F will "fix" the patient, compared to other treatments like Kuvan, which is much more expensive and less effective, but covered by insurance. Food is usually never covered by insurance. Tarini –There could be a push to insurance companies to cover other therapies. Not an option with current FDA and CMS structures for F&F. Many other states have similar F&F structures (fees), or appropriations (which we know goes away) or Title V. Some may question why does everyone who has a baby screened have to "pay for F&F" for those few who have a child needed F&F. It is similar to insurance – you are paying on the chance that your baby may have a metabolic condition. Degnin - The cost savings for treating disability and morbidity for untreated condition is much costlier. Tarini – articles on cost benefit for treating PKU research are readily available. Romitti – (specific to F&F) dealing with the legislators you need to realize that fee increases are often seen as taxes to some. Need to look at long term savings of NBS treatments and be prepared to discuss to the legislator's "perspective." Berberich - The opportunity for harm is present to every baby – that's what population based screening addresses.
Budget Proposals – IDPH	Early Hearing Detection and Intervention (EHDI) Requesting $5/specimen for program administration and follow-up activities. Currently an unfunded state mandate supported by ever-decreasing HRSA and CDC grant funds. They have had to lay off two people over the last two years. – Trout – what does the EHDI request pay for? Piper – IDPH EHDI staff time to conduct follow-up and surveillance activities that are currently being supported by other funding. Devereaux – if fee is increased for hearing screening, why not add to cover hearing aids/audiological services? Piper – hearing aids/audiological services activities were never a function of EHDI. It was a separate appropriation for services carried out by audiologists and similar providers passed through IDPH to another service provider. Iowa Newborn Screening Information System (INSIS) – Funding of $5 per specimen is requested from the NBS fee to support ongoing maintenance and hosting of the Iowa Newborn Screening Information System (INSIS). Currently funded through developmental funds and other piecemeal funding sources.
Budget Proposals – General discussion	How much does insurance cover now for NBS fee? Who bills for this? Who eats the costs? Piper – Hospitals submit the full fee amount to SHL. Hospitals then pass bill on to patients. Hospitals are reimbursed at whatever rate they have negotiated with the specific insurance companies the patients have. This may not be at the full fee amount, so hospitals "absorb" the difference. Usually the NBS fee is rolled into the "overall" global newborn service code (DRG) and not broken out as a stand-alone expense. Romitti – Is concerned that the Registry has never been considered for funding through NBS fee for provision of surveillance activities. It has been a longer standing program than even EHDI. When is CIDAC/CCID going to take care of all of its programs?
Other discussion	Beth – SMA was approved by SACHDNC. Goes to Secretary of DHHC. Interagency Coordinating Council may be next stop before Secretary's decision. Trout – Does it matter what SACHDNC says for Iowa's review or decision about whether to add a condition? Piper – no. If CIDAC and the IDPH decide to add a condition, they can.

Adjournment	Meeting adjourned at 2:02 pm.