CALL TO ORDER:
Rebecca Boyd Parrott called the meeting to order at 1:00 p.m. Rebecca Boyd Parrott, the new chairperson, introduced herself to the attendees. She is the Iowa Bar Association liaison to the Birth Defects Advisory Committee. She has been on the committee for several years.

MEMBERS PRESENT:
Rebecca Boyd Parrott, M. Peggy Stokes, Neil Mandsager, Greg Garvin, Representative Pat Murphy, Jeff Murray, Janet Williams, Linda Brown, Julie Curry; Nancylee Ziese, Roger Williamson; Jeffrey Lobas; Carol Johnson for Val Sheffield; Cathy Evers; Paul Romitti

MEMBERS ABSENT:
David A McInnes, Senator Kitty Rehberg, Michelle Hall, Mary Gilchrist; Jerry Wickersham

OTHER ATTENDEES:
Julie McMahon, Tonya Diehn, Christina Trout, Stan Berberich, Jenifer Carmody, Don Simmons, Judy Miller, Penny Grafton, Marcia Valbracht

APPROVAL OF MINUTES:
Nancylee Ziese requested that the July 20, 2001 minutes reflect that Jerry Wickersham stated that he did not support a newborn metabolic screening waiver for religious reasons. The minutes were approved with this amendment.

I. IDPH UPDATE
A. Budget/Administration Issues
Julie McMahon
The health department has been working on the FY02 budget deappropriation. Last week, a FY02 revision was submitted to the governor and his staff that reduced the IDPH budget by 1.9 million + dollars or 7%. The revision was in response to the governor’s wish to hold some state departments harmless (programs like K-12, Medicaid, Public Safety, and Emergency Management). Constitutionally, however, the governor can only advance a deappropriation or change in budget after the legislative session is dismissed if it is an across the board cut. The governor has now issued an Executive Order requiring a 4.3% “across the board” (ATB) cut effective November 1, 2001. At the health department, the reduction plans have looked at the department’s organizational units (e.g., Chronic Diseases, Elderly Wellness, and Child and Adolescent Wellness). Dr. Gleason gives the administrative staff direction as to programs within the unit that must be held harmless from any reductions. Overall, at the time the last revision was submitted to the governor, it was looking good for the Birth Defects Institute programs and the issues of interest to the BDAC. It is expected that there will be a special legislation session in early November. Julie sees a couple of options for legislation: 1) accept state plans for across the board cuts and move ahead or 2) make exceptions to cuts which could
result in further deappropriation to other programs. Whatever happens to the FY02 budget, it will have a definite bearing on the FY03 budget.

Redesign of government or reinvention or improvement of state government is occurring. Changes will allow for flattening of hierarchy and increased efficiency and effectiveness of state government. Central focus is how all changes would contribute to improved services for Iowans. Process started with 500 to 600 “blue-sky” ideas collected through a number of venues. Julie understands that now there are 120 ideas that are being explored as to how they would actually work. In early November, the governor, lieutenant governor and department directors will determine which ones advance. With this there may be some reappropriation after the initial deappropriation. It is both an exciting and stressful time for the health department.

B. Status Report on Administrative Rules
Tonya Diehn
The administrative rules were rewritten to add MCADD to the screening panel and to make the chapter clearer and inclusive of all programs with the BDI. The administrative rules were adopted by the Board of Health on September 12 and become effective on November 7.

INMSP
- Clarification of exceptions to specimen collection requirements, including responsibility for screening of transferred babies, home births.
- County registrar responsibility to inform families about screening. County registrar provides lay midwives, midwives, and families a home birth packet with a birth certificate worksheet and an INMSP brochure and collection form.
- Waiver specifics to help facilitate the lab or IDPH receiving the waiver for tracking and assurance purposes. Rita Swan asked for removal of the waiver at the public hearing. The Board of Health approved the chapter with the waiver provision.
- The policy for retention and disposal of newborn blood spots.

NMP section details program’s activities.

IBDR section details the birth defects surveillance policy, activities of registry, the responsibility of IDPH, notification of parents by the health department or a designee, and general policies for research proposals.

C. State Genetics Plan of Iowa
Tonya Diehn
The State Genetics Plan was provided to the attendees. Individuals were encouraged to take additional copies and to distribute them to interested individuals and organizations.

D. Genetics Implementation Grant
Tonya Diehn
The three-year grant with approximately $300,000 funding per year was awarded in June 2001 by HRSA, Maternal Child Health Bureau. It was written to address some of the state genetics plan recommendations and focuses on newborn screening and surveillance systems and programs serving newborns and their families such as Early ACCESS. The goals and objectives of the grant with the proposed activities were distributed by email with the agenda. There are several positions with this grant. The hiring for these positions is on hold. One position was filled temporarily with a consultant and this was for the information management position. He is working to develop a web-based vital record system for birth certificates. When IDPH is able to hire for positions, they will do so and this will include hiring the information management person into the department.
Jeff Murray asked if the web-based vital records system would tie in with the birth defects registry. Tonya indicated that it is expected that the vital records web-based system will facilitate the availability of timely aggregate data for other programs and improve integration capability between programs. The National Center of Health Statistics has revised the US standard birth certificate and changes are underway to the Iowa version to incorporate fields for newborn metabolic screening, newborn hearing screening, and barriers to prenatal care. Additional fields for NBS has been discussed for almost 10 years. The field for the barriers to prenatal care program has been place for a number of years. Tonya has asked Jill France, the Vital Records Director if a field for collecting the ICD-9 or ICD-10 final diagnosis code could be added to the Iowa birth certificate information. Paul Romitti indicated that the item would be helpful to IBDR as one surveillance source. Tonya addressed questions about the birth certificate including “above the line” and “below the line” items, accessibility to “below the line” information and its uses for public health research and planning.

II. PROGRAM OVERVIEWS

A. Regional Genetics Consultation Service

The program’s brochure was distributed. RGCS started in 1976 as a joint venture between IDPH and the Univ. of Iowa to provide comprehensive genetic services to the citizens of Iowa. The two components are comprehensive healthcare services (including evaluation, consultation, support and case management) and statewide education. The genetic personnel provide over 100 statewide education activities annually. The program currently has 6 genetic nurses/genetic counselors (4 full time positions, 2 half time) and 4 part-time physicians. Comprehensive genetic healthcare services are provided at 16 clinic sites. However, they are currently not holding clinics in Decorah and Atlantic due to decreased staffing. The clinics see patients of all ages and address issues spanning the whole life cycle. Demand is always increasing and they currently have a backlog that they can’t adequately address. Health care providers, educators and families make referrals. The clinic fees are based on sliding fee scale with billing to third party payers. Sixty percent of the families utilizing RGCS qualify for total reduction of the fee after insurance payment.

Jeff Murray asked about the nature of meeting the needs of the programs. Cathy responded that is both a staffing and financial issue. They are currently down one physician and one counselor but even with full staffing they would have difficult meeting the demand. Greg Garvin asked if a change in referral protocols would help to better streamline the process and suggested accepting referrals from health care providers only. Rebecca asked what percentage of the referrals were non-medical. Cathy did not have the figure with her but indicated they did determine this for their last needs assessment. Nancylee Ziese asked about the composition of the backlogged cases. Cathy responded that many of backlogged cases are children that were previously seen by the clinic for birth defects, genetic conditions, learning problems and other reasons that they haven’t been able to get back in for a follow-up visit. It is difficult seeing follow-up patients promptly because they are receiving two to three new referrals a day. Julie McMahon asked if there is a triage screening of the referrals. Cathy indicated that if they feel a patient is critical they would see them as soon as they can and try to see them in the closest clinic to their house. If it is of lower concern, the staff tells the individual when the RGCS will be in their area but also gives them the choice of traveling to one of the other clinic sites. Some of sites like Creston meet twice annually. They have 16 clinics in Des Moines a year at two sites, Broadlawn Medical Center and Des Moines University Tower Clinics. Dr. Mandsager asked if they have considered outsourcing their genetic load.
B. Neuromuscular Program  
Christina Trout  
The Neuromuscular and Related Genetic Disease Program was initiated a few years after the RGSC and for some of the same needs. The program was designed to be comprehensive in the services for these specialized kinds of patients and their families. The focus is primarily on the pediatric population but they also see adult patients, as there are not many adult neuromuscular physicians that understand the very complex diagnostic and long-term management issues of these disorders.

The distributed handout listed the disorders that qualify for neuromuscular services. Individuals have problems with their muscles or nerves and the common names are muscular dystrophy or peripheral neuropathies. These disorders are quite disabling and life-shortening and more complex than most neurologists typically follow in their clinics. Overall, 1 in 3000 individuals are affected with one these disorders. They try to screen their referrals carefully and only accept individuals how are highly likely to have a muscular and neurological disorder. Staff consists of Christina, the nurse coordinator and Dr. Matthews, a pediatric neurologist with specialities in genetics and neuromuscular conditions.

The neuromuscular clinic sites are Des Moines, Sioux City, Mason City, Dubuque and Waterloo. They also see individuals on a weekly basis in Iowa City. Services may include detailed evaluation, genetic testing, biopsy, treatment and management. Ongoing management of neuromuscular healthcare problems is the major emphasis of their clinics. They have a physical therapist at the field clinics and in Iowa City. Patients are living longer with new challenging problems including pulmonary management, community-based nursing services and psychosocial issues. They provide patient and family education including genetic counseling and assistance with advanced directives and living wills. They work closely with MDA. The program also utilizes a sliding fee scale. Services provided in clinic are reimbursed well but the vast majority of the services they provide to family are not reimbursable. The number of new patients has tripled since 1994. They have doubled the number of outreach patients in the last six years.

C. Iowa Birth Defects Registry  
Paul Romitti  
The registry is preparing their annual report. It will be released in January in conjunction with National Birth Defects Prevention Month. The registry was established in 1983 as a joint project of the IDPH and Univ. of Iowa and its primary mission is active surveillance. Field representatives go to hospitals and clinics throughout Iowa and cities in surrounding states that serve Iowans (i.e. Omaha, Sioux Falls, LaCrosse) and review medical records for birth defects. The registry tries to be comprehensive in their surveillance so as to identify any Iowa resident who has had a pregnancy affected by a birth defect. CDC ranks active surveillance as the highest level of surveillance. In the past and until the middle of this year, the registry used the Cancer Registry field representatives for their surveillance. These individuals were already out in the state abstracting records on any Iowa resident with a cancer diagnosis. However, the workload became too great and timely birth defects surveillance data was not being obtained.

The registry relies on federal grants for ninety percent of their surveillance and infrastructure budget so timely data is critical to assure funding. A small appropriation from the Board of Reagents covers ten percent of their operating budget. The registry was recently able to hire 5 abstractors with INMSP and MSAFP developmental funds and a timely turn around time is being achieved again. The registry is utilized for and participates in a number of research
projects including cardiac defects, Down syndrome, oral-facial clefts, and the NTD study with Roger Williamson. New to the registry in the last two years is their education and outreach unit. This is third part of their mission, to translate the surveillance and research findings back to the people of Iowa. The registry is working with the March of Dimes, Tonya and Jean at IDPH and other organizations to provide education and to begin outreach.

Neil Mandsager asked how could the physicians out in the state assist in making sure the registry data are accurate. Paul indicated that physicians could greatly facilitate the registry’s activities by responding to the registry’s requests for additional information about a diagnosis or clarification of a diagnosis. Neil asks it would be advantageous to notify the registry of birth defects they see prenatally and if there is a mechanism to do so. Paul responded that they do get some reports through the U of I OB amniocentesis programs and the MSAFP program and this process could be more formalized and inclusive. Jeff Murray indicated that the registry is really striving for 100% ascertainment and if the Des Moines Prenatal Clinic can provide the registry with information about their prenatal cases that would extremely helpful. Jeff and Paul will follow-up with Neil about this.

The registry performs passive consent for research studies. The local medical doctor of each child is contacted as a courtesy prior to contacting the family so that the physician can respond about the circumstances of the family and if they should not be contacted. The registry also contacts parents of a terminated pregnancy with a birth defect. For those cases, the registry asks the physician who performs this interruption to sign the letter prior to contacting the families. Both Neil and Roger Williamson have received these types of letters from the registry. Currently, neither physician personally notifies families about the registry. It was discussed that it may be more appropriate for physicians to be pro-active and inform families about the registry at the time of a prenatal diagnosis.

Janet Williams asked if the registry’s educational activities are targeting particular audiences or if are they a general contribution. The registry has been involved in activities such as the Folic Acid Council, March of Dimes, public health, lectures to different groups, and redesign of their web site. The web site is http://www.public-health.uiowa.edu/birthdefects. The National Birth Defects Prevention Network is in the final stages of approving a web site that will have state specific data for 47 conditions. The registry will have a link to this site and it will be accessible through the NBDPN web site. A question was asked about home births. The registry does not do home birth surveillance but they may obtain information on a child who was delivered at home if they were seen in the hospital or a clinic for their condition.

III. IOWA NEONATAL METABOLIC SCREENING PROGRAM

A. Overview of Program

Stan Berberich

MCADD is now part of the newborn metabolic screening panel and is being routinely reported. The expanded tandem mass spectrometry pilot study proposal was approved by the IDPH in mid-September and the pilot has been underway for three weeks. The health department is reviewing the biotinidase deficiency proposal. The laboratory is currently going ahead and working out the protocols for the testing so they are ready to go ahead with the pilot immediately after approval. Stan reports that the program has not seen an increase in the number of rejected specimens due to delay in transport with enhanced postal security measures.
B. MS/MS Expanded Panel Pilot Study Update

Don Simmons

The pilot study is screening for approximately 71 different markers or ratios to look at approximately 31 different disorders. They have had eight results that required follow-up for repeat testing for various indications. The laboratory has received repeat samples for two of these and these specimens tested negative. Don expects that as the pilot study progresses they will refine their cutoff values and the number of false positives will drop to around six to eight specimens a month. He also expects that 1 out of every 10 specimens followed up will be a true positive. Jeff Murray asked about the positive controls for this type for screening. Don answered that they have internal standards for the panel as well as positive controls for MCADD and a number of the other disorders. Their present data compares well with the other programs that have been doing the MS/MS expanded panel for a longer period of time. The majority of the time the laboratory can run the specimens all on the same day on the one MS/MS machine.

IV. INMSP BLOOD SPOT RETENTION POLICY

Tonya Diehn

The current policy states that the newborn blood spot specimens shall be held for one month and then incinerated unless kept for research use or program evaluation. Dennis Klein, the assistant medical examiner has asked for the review of this policy. He would like the BDAC and IDPH to consider a one-year retention period for newborn metabolic screening specimens. The medical examiners office performs a metabolic panel on all possible SIDS cases in Iowa. They send whatever post-mortem samples they are able to obtain to NeoGen. This testing sometimes comes back inconclusive, particularly with acyl carnitine profiles. A newborn blood spot specimen could allow for clarification of an inconclusive result or confirm a positive one. Recently Dennis had a case in which NeoGen reported a positive result for a specific metabolic disorder. The laboratory requested a newborn specimen for confirmation. Dennis asked Tonya whether the newborn specimen was still available. It was determined that the blood spot card was involved in a research study. The identifiable information has been removed, however, there was potential to link the card. The IDPH felt that because the card could not be linked back to identifiable information with 100% certainty, an attempt to retrieve the card shouldn’t be made. Dennis is aware that we are doing a pilot study for the expanded panel. Tonya asked if when the INMSP is performing a pilot study would be there a precedence to keep those cards for the duration of the study for the program’s confirmation as well as to meet the needs of the medical examiner.

It was asked if extended storage time would affect the validity of the testing. Don Simmons recently attended a MS/MS meeting in which research presented found that acyl carnitine levels can degrade at –20 C. He questioned the intent of NeoGen in its request for a newborn blood spot specimen. Jeff Murray believes that all newborn blood spot specimens should be stored and stored forever. Don Simmons also would like them stored forever but the storage constraints, the costs of storage, and the legal issues need to be worked out so make sure that the INMSP is protected and the uses are beneficial to the consumers. The past and current administration has opposed extended storage for the opposite legal and medical concern, that being, a disorder could have been diagnosed by the newborn blood spot specimen and it was missed. There other public health reasons for storing these specimens including additional pilot studies for risk factors in this state. The components for some of these disorders may not be detectable biochemically; however, molecular analysis could be done. It was discussed how could researchers and the program’s needs be met. Stan Berberich wonders if a small group should be brought together to look at the issues: the benefits, the purposes for storage, appropriate retention period, negative
aspects, medical and legal concerns, and financial cost. Jeff Murray motions for the appointment of a subcommittee to look into the long-term storage of newborn metabolic screening samples in the state and the issues regarding this storage. Paul Romitti seconded the motion. The committee unanimously voted to establish the subcommittee. Julie and Rebecca requested a wide representation on the subcommittee including consumers, families and legislators. Rebecca recommends involving the attorney general office in the discussions and the questions. Tonya will work to setup the subcommittee. Judy Miller, Pat Murphy, and Linda Brown indicated interest in participating in the subcommittee. Tonya shared with the committee that the new INMSP brochure was available and contains a statement about program evaluation and research use of the newborn screening blood spot specimen.

There was discussion about the current research project utilizing newborn screening blood spot cards and if the specimens were truly anonymized. Dr. Richard Smith is currently receiving cards stripped of the personally identifiable information for his Connexin-26 research study. The laboratory is keeping a log sheet of the bar code number of each sample provided to Dr. Smith. The research agreement indicates that when Dr. Smith identifies a Connexin-26 mutation in a newborn, the designated INMSP person would search the newborn hearing database to see if that newborn had a newborn hearing screen and what the result was. Dr. Smith and the newborn hearing screening personnel would not know the identity of that newborn, only the individual in INMSP would. Further discussion occurred about the policy for use of newborn screening specimens. The BDAC needs to see a research agreement when reviewing a research proposal for newborn screening blood spot cards. The Connexin-26 research agreement and protocol violates the formal definition for anonymized specimens. A motion was made to amend the role of the subcommittee to include review of the retention, disposition and use policy by Jeff Murray. Paul Romitti seconded the motion and the committee unanimously voted for the amendment.

V. MSAFP PROGRAM
A. Overview of Program

The screening program in pregnancy was started with alpha-fetoprotein (AFP) in 1984. AFP is very useful in detecting neural tube defects and other severe birth defects. Statistics kept since the program inception have consistently demonstrated that 1 in 12 to 1 in 15 fetuses whose mothers had elevated AFP levels have a neural tube defect or a very serious defined fetal anomaly. In the mid 80s, low AFP levels were found to be associated with Down syndrome. In 1987, the program was offering AFP screening to women under 35 to pick up Down syndrome. In 1990, the program began triple test screening (AFP, unconjugated estriol, and human chorionic gonadotropin). Three to four percent of women screen positive with the triple test. The screen has approximately a 60% detection rate for Down syndrome and detects other chromosome abnormalities as well but with lower detection rates. The Expanded MSAFP Program screens roughly 16,000 women/year for about 40% acceptance by pregnant women. In a month to six weeks, the program will include Smith-Lemli-Opitz (SLO) in the disorders they can screen for. The disorder is associated with very low estriol levels. Three women in 1000 will screen positive for SLO with 1 out of 60 resulting amniocentesis procedures demonstrating a fetus with SLO. Currently, the program is participating in a Foundation for Blood Research study and the screening algorithm has been worked out. The program is working on patient education materials.
B. Inhibin A Update

Stan Berberich updated the attendees about the inhibin-A pilot. He reports that the MSAFP laboratory personnel have completed their training on the equipment used to screen for inhibin. They are now determining medians for inhibin and estriol (which also can be run on the equipment) and validating the instrument and the reagents. Stan felt that in three to four weeks they should be begin quadruple screening (inhibin as well as the triple test markers). The addition of inhibin will significantly reduce the false positive rate as well as increase the detection rate of this screening.

C. Couple Carrier Screening for CF Proposal

The proposal was distributed by email prior to the meeting. Last month the American College of Obstetricians and Gynecologists sent all their members materials and guidelines for CF carrier screening. The American College of Obstetricians and Gynecologists, NIH and the American College of Medical Genetics' guidelines recommends that health care providers offer CF screening to: 1) individuals with a family history of CF, 2) reproductive partners of individuals who have CF, and 3) couples in whom one or both partners are Caucasian (includes Ashkenazi Jewish) and are planning a pregnancy or seeking prenatal care. The screening is to be made available to couples in other racial and ethnic groups. Physicians are encouraged to offer the screening at the time of the first prenatal visit. A 1988 survey performed by the Expanded MSAFP Program indicated that the majority of respondents would like a statewide program similar to MSAFP if CF screening were mandated. Jenifer has received multiple calls from physicians in last month regarding the recommendations and what they should do.

The initial phase of the pilot study will establish proficiency in DNA-based CF screening by testing 100 CAP samples. This testing is expected to take three months. The second phase will be determine patient interest and uptake by offering CF carrier screening to patients seen at the University of Iowa OB/GYN and the Des Moines Perinatal Center. Testing and genetic counseling would be provided to patients free of charge. They hope to perform testing and genetic counseling for 60 samples during this phase of the study. The budget attached to the proposal is requesting approximately $35,000 for the six-month study. The program would like to begin the pilot immediately.

Tonya shared feedback she received from other State Coordinators regarding how other states were addressing CF carrier screening. Washington, Florida and California indicated that they are not planning statewide Cystic Fibrosis carrier screening. Wisconsin and Alabama have plans to review and discuss the issue further. The California coordinator shared that statewide newborn screening for CF is a viable addition in California. Jenifer pointed out that Iowa is different then many states because they have a statewide MSAFP program. Roger Williamson interprets the Iowa Code to indicate an obligation to provide statewide CF carrier screening using the designated central laboratory, UHL. Both Jenifer and Roger stressed that offering CF carrier screening is now a standard of care.

The proposal generated much discussion. It was discussed whether this standard of care requires a statewide program and what benefits would such a program have for the citizens of Iowa. Two primary issues emerged from the discussion: the ability to provide genetic counseling to the number of carriers that potentially could be detected through CF couple carrier screening and whether the UHL itself needed to perform the testing. Insurance coverage, Medicaid coverage, cost of testing and assuring availability of testing to all that want it were
also discussed. Jenifer Carmody believes that the uptake of CF carrier screening will not be as high as MSAFP screening. She discussed that whether there is a statewide CF carrier screening program or not, the screening has to be offered and individuals will have to have genetic counseling. Possible resources for genetic counseling would include prenatal counselors with the Expanded MSAFP program and the Des Moines Perinatal Center, RGSC and the CF clinic personnel. It was asked whether utilizing genetic counselors from Genzyme, a national laboratory would be beneficial. Discussion about contracting to an outside laboratory for the testing portion of the program occurred especially if the uptake isn’t great. Suggestions were made to contract out the testing during the pilot study to determine utilization and use budget dollars to pay for testing rather than buying equipment.

Neil Mandsager motioned to approve the pilot study as proposed. Nancylee Ziese seconded the motion. Discussion of the motion raised several concerns about the pilot budget and proposal content. The budget has a lot of capital expenses for a minimum number of tests. It was questioned why it was necessary to purchase equipment for 160 tests especially if the UHL is not performing the tests during the pilot. The proposal indicates that Tom Winder of the U of I pathology department would be contracted to perform the laboratory testing for the pilot. He would also train Beth Albaugh of the MSAFP Program. A memorandum of understanding was not available at the meeting. It was asked if it would be better to contract out the testing and then save money to hire a genetic counselor to fill the genetic counseling needs of the program. Roger indicated that the equipment could be taken out of the budget and Stan agreed. However, with CF carrier screening being the standard of care, Stan indicates that his understanding was the pilot study was in part to determine the laboratory’s capability to do the testing and to validate, to manage it. It is argued that if the program is going to contract with Tom for the pilot that they are going to have to perform another pilot at the UHL to determine this information. Cathy Evers asked why couldn’t the program contract with Tom to do all the screening. Roger felt that politically that would be a dicey thing to do. Linda Brown asked why would you not charge during the pilot study to better access cost reimbursement rates and true patient uptake. Neil Mandsager felt that she raised valid points. Traditionally, a patient has not been charged during a pilot study. Linda asked for clarification for whether CF carrier screening is the standard of care. Greg Gavin indicated that currently for primary physicians it is not but standard now but will be. Roger believes that it will take some time before insurance covers this testing. The motion to approve the pilot study proposal was passed with a vote of 10 yes and 1 no.

VI. METABOLIC FORMULA FUNDING

Tonya Diehn

At the April 2000 meeting, Drs. Sheffield and Lobas proposed a $2.61 fee increase (Note: actual proposal to BDAC was for $2.00, the metabolic formula program later proposed $2.61) to the newborn metabolic screening fee to help pay for metabolic formula. The program has been unable to meet the financial costs of providing metabolic formula to all those in need. Their proposal was approved by the BDAC but rejected by IDPH. Mary Weaver and Jean Anderson then spoke with the Iowa Insurance Commissioner about mandatory insurance coverage for metabolic formula. The commissioner was not in favor of this and indicated that a mandate would cover only 25% of families with insurance and would raise insurance premiums. The Metabolic Formula Program now has specific guidelines and a slide fee scale application for program participants. In addition, Dr. Sheffield received a two-year grant through a private foundation to supplement the funding for metabolic formula. Mary Weaver had spoke with Dr. Sheffield and other individuals that the IDPH would try to solve this
problem. Tonya states that currently IDPH does not have a solution to the problem. The Metabolic Formula Program was recently moved into the Genetics Division and Carol Johnson is now the administrator of the program.

Dr. Lobas discussed the variability of insurance coverage for metabolic formula in the state. Wellmark and hawk-i (through Wellmark) no longer cover metabolic formula. Their pharmacy plan is now provided by Advance Paradigm. Pat Murphy stressed that IDPH and the program need to go back to Iowa Insurance Commissioner to enforce metabolic formula coverage. The Iowa Insurance Commissioner regulates Wellmark, John Deere, and Principal (which is 25% of the insurance market). The problem with enforcement occurs with self-insured policies or when the companies contract with a private company to manage their employees and their insurance fund. hawk-i can be enforced to pay for the formula. Linda asked if the Iowa Neonatal Metabolic Screening Program wants to go towards the direction of paying for treatment now. Judy Miller thinks metabolic formula is in a different category because for the other disorders, insurance pays for the necessary treatments. Linda asked about how other states cover metabolic formula. Judy indicated that all states have a metabolic formula program but there is variability in what each state covers. Illinois, for example, pays for formula for their life. Neil Mandsager asks if the Iowa Insurance Commissioner could make the decision that metabolic formula is a medicine not a nutritional supplement. The commissioner has indicated that the Iowa Code definition of a prescription drug doesn’t exclude metabolic formula. Included in the definition, is that a prescription drug can’t not be purchased by an individual on their own. However, some insurance companies are interpreting the definition of prescription differently than others. Pat Murphy discussed that if the legislation were to pass a bill covering metabolic formula it would only pertain to the regulated insurance companies.

Jeffrey Murray stressed that for exactly the loophole that Judy Miller mentioned, we have to assure that these individuals get this formula. We have a social contract with them as we are testing them for the disorder and it is unconscionable to think that we could tell individuals to go bankrupt trying to pay for it or go without. We have to find a way to pay for metabolic formula. Rebecca Parrott raised the question as to what was the role of or the charge of BDAC for addressing with this issue. Individuals asked what the Iowa Code says regarding treatment. The Iowa Code states “The department (IDPH) shall initiate, conduct, and supervise screening programs to discover genetic birth defects and related diseases and to prevent or treat the defects or diseases.

Discussion about the financial status of the program occurred. The private foundation grant funds currently supplementing the program will end in March 31, 2002. Carol Johnson estimated that the Metabolic Formula Program requires a $150,000 per year to cover metabolic formula and administrative costs. The CHSC provides the program with a $30,000 per year allocation. They receive reimbursement from some third-party payers but it doesn’t begin to cover the total cost of the program. The formula program uses the same sliding fee scale as the RGSC. It was estimated that 30 to 40 percent of the metabolic formula is given away for free. The cost per child for formula is approximately $2000.00-$5000.00. These children also require low protein foods that are very expensive for families and are not covered by insurance. The American Academy of Pediatrics recommends that the PKU patients receive metabolic formula for life.
Discussion occurred about where this issue falls, is the responsibility of the newborn screening program, BDAC, IDPH or another arena. Julie McMahon indicated that Tonya and herself have been working with a number of individuals at IDPH regarding this issue. When they were exploring possible solutions, they hadn’t thought of the avenue Pat Murphy discussed and this could certainly help with a portion of the families. Other possibilities include WIC blanket waivers, Medicaid eligibility, federal waivers, fund reallocation, and as a last resort, developmental funds. Carol discussed that several of the PKU families are Amish and that they present a unique situation. The University business office will be working with the elders of these families’ communities to establish a payment plan. Carol discussed that the PKU population has a poor understanding of the metabolic formula program. Julie McMahon that the program is moving in the right direction but we need to look at all angles. Greg Gavin asked about formula company assistance for families. Judy indicated that the assistance was short-term. WIC does pay for formula for children up to the age of five.

It was discussed why the BDAC couldn’t advance the previous proposal to increase the newborn screening fee. A number of improvements have been made to the program including the development of guidelines. Julie stated that there was no question that the increase would solve the problem. However, both Julie and Pat Murphy indicated that the issue is how any fee increase on anything during the present budget climate would be perceived. Pat discussed that a fee increase requiring a legislative action would be difficult. The BDAC could not come to any consensus. The members expressed frustration about what more they could do. It was agreed that BDAC would again draft a letter to Dr. Gleason with their recommendations and continued support for a newborn screening fee increase. Julie said the letter should outline the strides the program has made, explore insurance and waiver coverage and stress social contract.

VII. ADJOURNMENT
The meeting was adjourned at 4:45 PM.

VII. NEXT MEETING INFORMATION
The next meeting will be held on Friday January 18, 2002 from 1:00 PM to 4:00 PM at the Wells Fargo Bank-Sullivan Room in Grinnell, Iowa, weather permitting.

Submitted by Tonya Diehn, finalized 11/16/01, corrected 3/02.