

2021 SENATE HUMAN SERVICES

SB 2224

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

SB 2224
1/25/2021

A BILL for an Act to create and enact a new section to chapter 50-24.1 of the North Dakota Century Code, relating to medical assistance coverage of metabolic supplements.
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Madam Chair Lee opened the hearing on SB 2224 at 9:00 a.m. All members present: Senator Lee, Senator K. Roers, Senator Hogan, Senator Clemens, Senator Anderson, Senator O. Larsen.

Discussion Topics:

- Private insurance coverage for supplements
- Adult and children coverage
- Metabolic diet V.S. supplements
- Age of 18 V.S. 21 in the fiscal note

[9:00] Senator Dick Dever, District 32. Introduced SB 2224 and provided testimony #2567 in favor.

[9:06] Courtney Koebele, Executive Director, North Dakota Medical Association. Provided testimony #2441 in favor.

[9:12] Kari Casas, Biochemical Geneticist and Metabolic Consultant for the ND Newborn Screening Program, Sanford Health. Provided testimony #2325 in favor.

[9:19] Brendan Joyce, Pharmacy Administrator, Department of Human Services. Provided testimony #2521 in favor.

[9:30] Donene Feist, Executive Director, Family Voices of North Dakota. Provided testimony #2371 in favor.

Additional written testimony: (2)

Joan Connell, Pediatrician. Provided written testimony #2461 in favor.

David Boeck, Lawyer, Protection & Advocacy Project. Provided written testimony #2699 in favor.

Madam Chair Lee closed the hearing on SB 2224 at 9:38 a.m.

Justin Velez, Committee Clerk

Testimony on SB 2224
Senator Dick Dever
January 25, 2021
Senate Human Services Committee

Madam Chair, members of the Committee, I am Dick Dever, Senator from District 32, here in Bismarck.

SB 2224 simply provides that Metabolic Supplements be covered through Medicaid. I know that the Supplements are necessary and expensive. for children who need them. This bill comes at the recommendation of the Medicaid Advisory Council.

My first session in the Legislature was in 2001. I recall one morning as I walked down the hall on the ground floor, I was approached by a Mother with three small children. She educated me on metabolic diseases and the need for very expensive, but necessary, food. The bill was Senate Bill 2239. Senator Judy Lee was one of the co-sponsors. It passed unanimously in both chambers.

Later in the session, we had the bill that required that any insurance mandate be applied to the PERS plan for the first two years. The bill failed by one vote. I voted no. Senator Gary Nelson asked me why and asked me if I would change my vote on reconsideration. I told him about that Mother and that I didn't think that they should have to wait two years for something so critical to their health. He told me we can make exceptions as they come up. We do as priorities come up.

If I was to make any pretense at having any expertise on this issue, I would stand in stark contrast to those who will follow who actually do.

I am happy to respond to any questions, but I am prepared only to encourage your favorable consideration of the bill.



Senate Human Services Committee

SB 2224

January 25, 2021

Chair Lee and Committee Members, I am Courtney Koebele, the Executive Director of the North Dakota Medical Association. The North Dakota Medical Association is the professional membership organization for North Dakota physicians, residents, and medical students.

NDMA supports SB 2224 and the reimbursement for metabolic supplements by ND Medicaid.

Federal regulations establish a committee to advise the state's Medicaid agency and its Medicaid director on health and medical care services. This committee is called the Medicaid Medical Advisory Committee (MMAC).

This year, North Dakota's MMAC created a Codes/Services Review sub-committee to offer recommendations to Medicaid for additional coverage for applications for coverage of seven different codes and services. That committee consisted of eleven members from the MMAC. The MMAC codes and services sub-committee met five times over the course of the summer to review the codes submitted. The committee received expert presentations on all the issues, and reviewed the detailed applications and attachments explaining the need for the services. The committee scored each service on seven factors: cost, number of patients impacted, whether it was covered by private insurance, proven efficacy, essential for health and well-being; whether it was a noncovered essential component of a service that is covered by Medicaid; and finally whether the service is covered by other insurance or organizations.

The subcommittee rated this coverage high because the supplements are life sustaining and the relatively low number of people that would need to receive them.

NDMA would support any amendments to make the application of this narrower and more precise.

Thank you for the opportunity to testify today. I would be happy to answer any questions.



January 23, 2021

Department of Medical Genetics
737 Broadway North, Route 1220

Fargo, ND 58122
701.234.2362
701.234.2995 (fax)

Dear North Dakota Senate Human Services Committee Members,

I'm writing in support of SB 2224, for coverage of metabolic supplements which are medically necessary for standard treatment for individuals with inborn errors of metabolism. For many years, North Dakota newborns with phenylalanine hydroxylase deficiency (also known as phenylketonuria or PKU) have received phenylalanine-free metabolic formula through the North Dakota state formula program, which has prevented devastating neurological disease among these individuals. With growth and diversification of our state's population, improvements and additions to our state newborn screening panel, and advancements in the field of clinical biochemical genetics, there are now North Dakota newborns being diagnosed with a wide variety of other treatable inborn errors of metabolism. These babies deserve equitable access to metabolic formulas and supplements which might be life-saving and/or may provide protection against neurological disease, vision loss, hearing loss, and other medical complications. Below are some examples of metabolic supplements which are medically necessary and standard in the treatment of individuals with inborn errors of metabolism.

Hydroxycobalamin, when administered intramuscularly, dramatically improves metabolic function in individuals with vitamin B12-responsive forms of methylmalonic acidemia, as well as individuals with homocystinuria. I am aware of at least two North Dakota children who require hydroxycobalamin injections, one for treatment of Cobalamin A complementation type methylmalonic acidemia, and the other for treatment of combined methylmalonic acidemia and homocystinuria due to defects in adenosylcobalamin and methylcobalamin synthesis. These disorders, when untreated, may result in metabolic encephalopathy, stroke, seizures, vision, loss, renal disease, and even death.

Biotin, given orally, is the sole treatment required to prevent medical complications of biotinidase deficiency. If untreated, individuals with biotinidase deficiency may develop intellectual disability, seizures, vision loss, hearing loss, hair loss, and skin disease. Several North Dakota newborns have been diagnosed with biotinidase deficiency and are being successfully treated with biotin. Families are typically paying out of pocket for this medically necessary treatment with biotin.

Thiamine, given orally, is used for treatment of individuals with thiamine-responsive maple syrup urine disease (MSUD). Among such individuals, thiamine increases the activity of branched-chain alpha-keto acid dehydrogenase. This prevents accumulation of leucine and associated metabolic encephalopathy, seizures, coma, and even death. There are at least two North Dakota residents with MSUD.

Riboflavin, given orally, is used for treatment of individuals with multiple acyl-CoA dehydrogenase deficiency (MADD) and multiple different mitochondrial diseases. Riboflavin may boost activity of flavoenzymes which are deficient in such disorders. Treatment with riboflavin may therefore prevent complications such as metabolic acidosis, skeletal myopathy, cardiomyopathy, neuropathy, seizures, coma, and even death. Patients with MADD and mitochondrial diseases often pay out of pocket for riboflavin and other components of their “mitochondrial cocktails”, which are essential for preventing metabolic crises and progression of their disease.

Thank you, in advance, for consideration of the medical needs of North Dakotans with inborn errors of metabolism, in particular those diagnosed via the North Dakota state newborn screening program.

Sincerely,

Kari Casas, MD

Clinical Associate Professor, Department of Pediatrics, UND School of Medicine & Health Sciences
Medical Genetics and Metabolism, Sanford Broadway Clinic

Testimony
Senate Bill 2224 - Department of Human Services
Senate Human Services Committee
Senator Judy Lee, Chairman

January 25, 2021

Chairman Lee and members of the Human Services Committee, I am Brendan Joyce, the pharmacy administrator for the Department of Human Services (Department). I appear today to provide testimony on Senate Bill 2224.

The Department does have the ability to pay for the products that are not drugs if directed by the 2021 legislature. Please note that with covered outpatient drugs, Medicaid is protected from pricing issues through the Medicaid Drug Rebate Program which ensures that all products meet FDA requirements, Medicaid receives the best pricing offered to any payer, and inflation is limited to the consumer price index. Also, there is federal pricing applied to essentially all covered outpatient drugs to equalize pricing across the nation. There are none of the above protections for the products that are the subject of SB 2224.

The fiscal note for this bill was prepared based on information provided to DHS by the Department of Health. With this information, the Department made the following presumptions when preparing the fiscal note:

- Coverage would be limited to recipients under the age of 18,
- Products would be limited to hydroxocobalamin, thiamine, riboflavin, and biotin
- The Department would have the ability to work with DoH to select cost effective products for coverage

Any changes to the above presumptions would require a modified fiscal note.

This concludes my testimony, and I am happy to answer any questions you may have.

Senate Bill 2224- In Support
Senate Human Services Committee
67th Legislative Assembly of North Dakota
January 23, 2021

Chairwoman Lee and members of the Senate Human Services Committee
Members

My name is Donene Feist and I am the Executive Director for Family Voices of North Dakota. As the Director of Family Voices we have assisted many families who have a child or youth with a metabolic disorder.

I stand to support Senate bill 2224. I am also a member of the Medicaid Medical Advisory Committee and Services/Codes subcommittee which reviewed and evaluated requests of metabolic supplements.

Currently, due to unavailability of New Drug Application numbers (NDAs) for certain supplements, Medicaid does not cover the hydroxycobalamin (vitamin B12) injection product necessary to treat infants/children with methylmalonic acidemia, a metabolic disease in which some subtypes are treated by injections of vitamin B12.

Failure to treat can result in a buildup of toxic substances in the body that result in a decompensation event. Note that hydroxycobalamin injection must be compounded to be dosed correctly in infants and children. This means that currently Medicaid will pay for this medication when infants and children are hospitalized but will NOT pay for infants and children to receive this daily medication when outside of the hospital.

Additional examples of metabolic supplements without NDAs that are not covered by Medicaid but are necessary to treat particular metabolic diseases include: biotin (vitamin B7) for biotinidase deficiency (given orally to prevent intellectual disability, seizures, vision and hearing loss, hair loss, and skin disease), riboflavin (vitamin B2) for diseases affecting metabolism of fat, protein and carbohydrates (given orally to prevent cardiac problems, seizures and other nerve disease, coma, and even death).

Thiamine (vitamin 1) for Maple Syrup Urine Disease (to prevent encephalopathy, seizures, coma, and death), and ADEK, a vitamin supplement that provides higher doses of the fat soluble vitamins A, D, E, and K for patients with a variety of malabsorption conditions, including cystic fibrosis.

The cost of these supplements is relatively insignificant compared with the cost of formula and other medications necessary for disease management- many of which *are* covered by Medicaid-and certainly *much* less expensive than emergency department visits and hospitalizations associated with suboptimal treatment of any/all of these diseases.

Therefore, the subcommittee recommended that Medicaid cover metabolic supplements without NDAs in cases where metabolic supplements are part of standard recommendations for treatment but no suitable product with a NDA number is available for use.

While I am no expert on metabolic supplements, I do believe we at Family Voices are very cognizant on family's need and the support they receive.

Many families struggle to put food on the table, many of the families who have an infant or child who need these supplements long term without access to them due to costs, clearly the child's health would be in jeopardy. Particularly when one or more is needed to treat the metabolic disorder.

On a personal note, I take many supplements due to an autoimmune disorder. I know what the cost of supplements are. Before I prepared my testimony, I thought of years past, when we were not financially able to support those costs and what a strain it would have put on us as a family financially. Not to mention the years it took to finally reach some sort of diagnosis.

Additionally, as you know I have a now adult son with a disability. While the scenarios are not the same, the financial impact of his diagnosis, many times left us literally unable at times to afford necessities. Food, clothing, shelter. Many times we were juggling who was going to get paid for the month, what we could postpone till the next paycheck or can we ask our parents to help us. The economic hardships that families are under now in 2021 are much more significant than they were when we were raising our son. I can't imagine what it would feel like, having this loom over your head month after month after month. The "what if's" would be detrimental.

As a mom, this would be heart wrenching knowing that these supplements may mean life and death, or that without them, developing a compounded illness or intellectual disability, all of which increase the long term costs for care.

Most of our children don't fit a mold. All are uniquely their own, and many have multiple diseases or disorders so rare that often doctors have never seen. Early on families realize with a heavy heart, the world we live in isn't built for our children.

Each and every day families are fighting someone about some aspect of their care. It could be a doctor, nurse, therapist, educator, or an insurance company. Every day families launch battles for what we know our children need to thrive, and sometimes our fight ends in defeat. We cry in our bedrooms at night. In the dead of night, many families lie awake, overcome by fear of the unknown.

Every day many families are fighting a battle against a disability, disease or chronic illness that we will never beat. Most of families know the very real implications of what can happen to our children at any given time. All we want is for our children to not have to fight so hard to simply be. Families need support often to get from point a to point b. This is an ever fluid and changing environment.

Families are not looking for handouts, but they do often need a rope to hang on to, to keep from drowning in an every changing system. Let us be sure we are supporting our most vulnerable children and families.

Please support SB 2224, for children with a metabolic disorder, their life could be dependent upon it.

Donene Feist
FVND Director
701-493-2634; fvnd@drtel.net



Senate Bill 2224-In Support
 Sixty-seventh Legislative Assembly
 Human Services Committee
 January 25, 2021

Good morning Chairman Lee, Vice Chair Roers, and Human Services Committee members,
 My name is Joan Connell. As a pediatrician and member of the Medicaid Medical Advisory Committee, I am requesting a Do-Pass for Senate Bill 2224. Passage of this bill would provide reimbursement by Medicaid for a smattering of metabolic supplements that are necessary for treatment of metabolic diseases but currently ineligible for reimbursement by Medicaid. While there are few metabolic supplements on this list, and few diseases with a very small number of patients, both points in which passage of this bill would result in a relatively insignificant increase in Medicaid expenditures, the economic impact on patients and their families is sizable. Patients and their providers have previously attempted alternative avenues for obtaining Medicaid reimbursement for these necessary treatments, including submission of appeals, completion of SFN 905 Medicaid forms, and recognition of this as a necessary service with subsequent reimbursement through Medicaid’s EPSDT program, all to no avail. Hence, these patients are relying on your legislative efforts so that Medicaid fulfills its obligation to provide necessary treatments to those who qualify. Below is a table that lists the current metabolic supplements necessary for patients but uncovered by Medicaid. While I am in clinic seeing patients so unable to be here with you today, I am available via this email to answer any questions you may have regarding this issue that is so important for this subset of patients.

Cystic Fibrosis Specific Supplements: These vitamins contain the appropriate dosing for people with cystic fibrosis and other related fat- malabsorption conditions (these are needed in higher quantities than standard vitamins) >150% RDA	Metabolic Condition Supplements: These supplements are necessary for quality of life for people affected with a metabolic condition. The dosing is often greater than if the general population was ingesting as a supplement. Not taking these is not an option for people with these conditions.		
MVW Complete Formulation (D3000 Chewables, D3000 Softgels, D5000 Softgels)	Alpha lipoic acid (fatty acid)		
AquADEKs	Betaine (amino acid)		
Vitamax	Biotin (Vitamin)		
ChoiceFul	B12 (Cobalamin)injections (vitamin that impacts fatty and amino acid metabolism)		
Libertas ABDEK	Coenzyme Q		
	Creatine monohydrate(treatment of impaired production of creatine)		
	Carnitine		
	Folic Acid		

	Hydroxocobalamin (B12 _a) (tx of fatty acid disorders)		
	Levocarnitine		
	Pyridoxine (B6) (regulation of the balance of amino acids)		
	Riboflavin		
	Thiamine(B1)(metabolism of glucose)		
AMINO ACID SUPPLEMENTATION:			
Alanine	L-Alanine	Phenylalanine	L-Phenylalanine
Arginine*	L-Arginine*	Proline*	L-Proline*
Asparagine	L-Asparagine	Serine*	L-Serine*
Aspartic acid	L-Aspartic acid	Threonine	L-Threonine
Cystine*	L-Cystine*	Tryptophan	L-Tryptophan
Glutamic acid	L-Glutamic acid	Tyrosine*	L-Tyrosine*
Glutamine*	L-Glutamine*	Valine	L-Valine

*-conditional amino acids, usually not essential except in times of illness or stress

Senate Human Services Committee
Sixty-Seventh Legislative Assembly of North Dakota
Senate Bill No. 2224
January 25, 2021

Good morning, Chairman Lee and Members of the Senate Human Services Committee. I am David Boeck, a State employee and a lawyer for the Protection & Advocacy Project. The Protection & Advocacy Project is an independent state agency that acts to protect people with disabilities from abuse, neglect, and exploitation, and advocates for the disability-related rights of people with disabilities.

As a former member of the state Medicaid Medical Advisory Committee (MMAC), I have great interest in the recommendations for legislation from the MMAC's Codes/Services Review sub-committee. I have seen its December 4, 2020 letter to you and to other legislators.

I am impressed with the makeup of the Subcommittee, its analytical process, and its recommendations that led to SB 2224. SB 2224 would address one of two highest priority needs identified for the North Dakota Medicaid program.

P&A enthusiastically supports the Subcommittee's work and SB 2224.

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

SB 2224
2/1/2021

A BILL for an Act to create and enact a new section to chapter 50-24.1 of the North Dakota Century Code, relating to medical assistance coverage of metabolic supplements.
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Madam Chair Lee opened the discussion on SB 2224 at 2:44 p.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens. Absent: O. Larsen.

Discussion Topics:

- Proposed amendment

[2:45] Jonathan Alm, Attorney, Department of Human Services. Provided committee with proposed amendment (testimony #6822).

Senator Anderson moves to **ADOPT AMENDMENT 21.0653.01001.**
Senator Hogan seconded.

Voice vote- motion passed.

Senator Hogan moves **DO PASS, AS AMENDED, REREFER TO APPROPRIATIONS.**
Senator Clemens seconded.

Senators	Vote
Senator Judy Lee	Y
Senator Kristin Roers	Y
Senator Howard C. Anderson, Jr.	Y
Senator David A. Clemens	Y
Senator Kathy Hogan	Y
Senator Oley Larsen	ABSENT

The motion passed 5-0-1.

Senator Anderson will carry SB 2224.

Additional written testimony: N/A

Madam Chair Lee closed the discussion on SB 2224 at 2:48 p.m.

Justin Velez, Committee Clerk

February 1, 2021

PROPOSED AMENDMENTS TO SENATE BILL NO. 2224

Page 1, line 7, remove "that does"

Page 1, replace lines 8 through 10 with "if:

1. The metabolic supplement has been identified and agreed to be covered through an agreement between the department and the state department of health;
2. The metabolic supplement is part of a standard recommendation for treatment;
3. A suitable metabolic supplement that is a covered outpatient drug is not available;
4. The individual is under nineteen years of age; and
5. Payment is made at a rate determined by the department."

Renumber accordingly

REPORT OF STANDING COMMITTEE

SB 2224: Human Services Committee (Sen. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** and **BE REREFERRED** to the **Appropriations Committee** (5 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). SB 2224 was placed on the Sixth order on the calendar.

Page 1, line 7, remove "that does"

Page 1, replace lines 8 through 10 with "if:

1. The metabolic supplement has been identified and agreed to be covered through an agreement between the department and the state department of health;
2. The metabolic supplement is part of a standard recommendation for treatment;
3. A suitable metabolic supplement that is a covered outpatient drug is not available;
4. The individual is under nineteen years of age; and
5. Payment is made at a rate determined by the department."

Renumber accordingly

PROPOSED AMENDMENTS TO SENATE BILL NO. 2224

Page 1, after line 6, replace the remainder of the bill with:

“Medical assistance coverage must include coverage of a metabolic supplement,

if:

1. The metabolic supplement has been identified and agreed to be covered through an agreement between the department and the state department of health;
2. The metabolic supplement is part of a standard recommendation for treatment;
3. A suitable metabolic supplement that is a covered outpatient drug is not available;
4. The individual is under the age of nineteen years of age; and
5. Payment is made at a rate determined by the department.”

Renumber accordingly

2021 HOUSE HUMAN SERVICES

SB 2224

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

SB 2224
3/8/2021 2:11 PM

Relating to medical assistance coverage of metabolic supplements

Chairman Weisz called the committee hearing to order at 2:11 p.m.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	A
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Standard treatment
- Medicaid coverage
- Special Health Services

Courtney Koebele, Executive Director North Dakota Medical Association (2:11) testified in favor and submitted testimony #7667.

Sen. Dick Dever, District 32 (2:14) introduced the bill.

Donene Feist, Executive Director Family Voices of North Dakota (2:17) testified in favor and submitted testimony #7660.

Brendan Joyce, Pharmacy Administrator Department of Human Services (2:26) testified in opposition and submitted testimony #7725.

Kari Casas, Medical & Biochemical Geneticist Sanford Health (2:37) testified in favor and submitted testimony #7827.

Additional written testimony: #7565 & #7773

House Human Services Committee

SB 2224

3/8/2021 2:11 PM

Page 2

Chairman Weisz adjourned at 2:39 p.m.

Tamara Krause, Committee Clerk



House Human Services Committee

SB 2224

March 8, 2021

Chairman Weisz and Committee Members, I am Courtney Koebele, the Executive Director of the North Dakota Medical Association. The North Dakota Medical Association is the professional membership organization for North Dakota physicians, residents, and medical students.

NDMA supports SB 2224 and the reimbursement for metabolic supplements by ND Medicaid.

Federal regulations establish a committee to advise the state's Medicaid agency and its Medicaid director on health and medical care services. This committee is called the Medicaid Medical Advisory Committee (MMAC).

This year, North Dakota's MMAC created a Codes/Services Review sub-committee to offer recommendations to Medicaid for additional coverage for applications for coverage of seven different codes and services. That committee consisted of eleven members from the MMAC. The MMAC codes and services sub-committee met five times over the course of the summer to review the codes submitted. The committee received expert presentations on all the issues, and reviewed the detailed applications and attachments explaining the need for the services. The committee scored each service on seven factors: cost, number of patients impacted, whether it was covered by private insurance, proven efficacy, essential for health and well-being; whether it was a noncovered essential component of a service that is covered by Medicaid; and finally whether the service is covered by other insurance or organizations.

The subcommittee rated this coverage high because the supplements are life sustaining and the relatively low number of people that would need to receive them.

Thank you for the opportunity to testify today. I would be happy to answer any questions.

Senate Bill 2224- In Support
Senate Human Services Committee
67th Legislative Assembly of North Dakota
March 8, 2021

Chairman Weisz and members of the Senate Human Services Committee Members

My name is Donene Feist and I am the Executive Director for Family Voices of North Dakota. As the Director of Family Voices we have assisted many families who have a child or youth with a metabolic disorder.

I stand to support Senate bill 2224. I am also a member of the Medicaid Medical Advisory Committee and Services/Codes subcommittee which reviewed and evaluated requests of metabolic supplements.

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Failure to treat can result in a buildup of toxic substances in the body that result in a decompensation event. Note that hydroxycobalamin injection must be compounded to be dosed correctly in infants and children. This means that currently Medicaid will pay for this medication when infants and children are hospitalized but will NOT pay for infants and children to receive this daily medication when outside of the hospital.

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The cost of these supplements is relatively insignificant compared with the cost of formula and other medications necessary for disease management- many of which *are* covered by Medicaid-and certainly *much* less expensive than emergency department visits and hospitalizations associated with suboptimal treatment of any/all of these diseases.

Therefore, the subcommittee recommended that Medicaid cover metabolic supplements without NDAs in cases where metabolic supplements are part of standard recommendations for treatment but no suitable product with a NDA number is available for use.

While I am no expert on metabolic supplements, I do believe we at Family Voices are very cognizant on family's need and the support they receive.

Many families struggle to put food on the table, many of the families who have an infant or child who need these supplements long term without access to them due to costs, clearly the child's health would be in jeopardy. Particularly when one or more is needed to treat the metabolic disorder.

On a personal note, I take many supplements due to an autoimmune disorder. I know what the cost of supplements are. Before I prepared my testimony, I thought of years past, when we were not financially able to support those costs and what a strain it would have put on us as a family financially. Not to mention the years it took to finally reach some sort of diagnosis.

Additionally, as you know I have a now adult son with a disability. While the scenarios are not the same, the financial impact of his diagnosis, many times left us literally unable at times to afford necessities. Food, clothing, shelter. Many times we were juggling who was going to get paid for the month, what we could postpone till the next paycheck or can we ask our parents to help us. The economic hardships that families are under now in 2021 are much more significant than they were when we were raising our son. I can't imagine what it would feel like, having this loom over your head month after month after month. The "what if's" would be detrimental.

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Families are not looking for handouts, but they do often need a rope to hang on to, to keep from drowning in an every changing system. Let us be sure we are supporting our most vulnerable children and families.

Please support SB 2224, for children with a metabolic disorder, their life could be dependent upon it.

Donene Feist
FVND Director
701-493-2634; fvnd@drtel.net



Testimony
Engrossed Senate Bill 2224 - Department of Human Services
House Human Services Committee
Representative Robin Weisz, Chairman

March 8, 2021

Chairman Weisz and members of the Human Services Committee, I am Brendan Joyce, the pharmacy administrator for the Department of Human Services (Department). I appear today to provide testimony on Engrossed Senate Bill 2224.

The Department worked with the Senate Human Services Committee, the Department of Health, and physicians to help come to the current version of this bill. The Department believes that these changes will allow for appropriate and fiscally responsible additions in products that are covered for patients in need. The existing fiscal note reflects the anticipated costs.

For clarification, the products discussed within this bill are not covered outpatient drugs so there are no drug rebates that come into play, nor are there the inherent protections in pricing and inflation of that pricing that comes with the drug rebate program. Therefore, the approach proposed in Engrossed Senate Bill 2224 is a very sound approach to the process for adding coverage of these products.

This concludes my testimony, and I am happy to answer any questions you may have.



March 8, 2021

Department of Medical Genetics
801 Broadway North, Route 1221
Fargo, ND 58122
701.234.2362
701.234.2995 (fax)

Dear North Dakota Legislators,

I'm writing in support of the SB 2224 request for medical assistance coverage of metabolic supplements which are medically necessary for standard treatment for individuals with inborn errors of metabolism.

It has been my pleasure to work with the North Dakota Newborn Screening Program over the past seven years, identifying and treating babies with inborn errors of metabolism. Through the efforts of Program Director Joyal Meyer RN, MSN and Follow-Up Coordinator Amy Burke RN, the North Dakota Newborn Screening Program tracks these children and works to ensure that they continue to receive medically necessary treatments. It is truly rewarding to see these children growing and thriving in our schools and communities. The investment of covering medically necessary metabolic supplements for individuals with inborn errors of metabolism is returned manyfold in avoiding devastating and costly medical complications in these individuals.

Thank you, in advance, for consideration of the medical needs of North Dakotans with inborn errors of metabolism, in particular those diagnosed via the North Dakota state newborn screening program.

Sincerely,

Kari Casas, MD

Clinical Associate Professor, Department of Pediatrics, UND School of Medicine & Health Sciences

Medical Genetics and Metabolism, Sanford Broadway Clinic

Senate Bill 2224-In Support
 Sixty-seventh Legislative Assembly
 Human Services Committee
 March 8, 2021

Good morning Chairman Weisz, Vice Chair Rohr, and Human Services Committee members,
 My name is Joan Connell. As a pediatrician and member of the Medicaid Medical Advisory Committee, I am requesting a Do-Pass for Senate Bill 2224. Passage of this bill would provide reimbursement by Medicaid for a smattering of metabolic supplements that are necessary for treatment of metabolic diseases but currently ineligible for reimbursement by Medicaid. While there are few metabolic supplements on this list, and few diseases with a very small number of patients, both points in which passage of this bill would result in a relatively insignificant increase in Medicaid expenditures, the economic impact on patients and their families is sizable. Patients and their providers have previously attempted alternative avenues for obtaining Medicaid reimbursement for these necessary treatments, including submission of appeals, completion of SFN 905 Medicaid forms, and recognition of this as a necessary service with subsequent reimbursement through Medicaid’s EPSDT program, all to no avail. Hence, these patients are relying on your legislative efforts so that Medicaid fulfills its obligation to provide necessary treatments to those who qualify. Below is a table that lists the current metabolic supplements necessary for patients but uncovered by Medicaid. Thank you for your consideration. I am available via this email to answer any questions you may have regarding this issue that is so important for this subset of patients.

Cystic Fibrosis Specific Supplements: These vitamins contain the appropriate dosing for people with cystic fibrosis and other related fat- malabsorption conditions (these are needed in higher quantities than standard vitamins) >150% RDA	Metabolic Condition Supplements: These supplements are necessary for quality of life for people affected with a metabolic condition. The dosing is often greater than if the general population was ingesting as a supplement. Not taking these is not an option for people with these conditions.		
MVW Complete Formulation (D3000 Chewables, D3000 Softgels, D5000 Softgels)	Alpha lipoic acid (fatty acid)		
AquADEKs	Betaine (amino acid)		
Vitamax	Biotin (Vitamin)		
ChoiceFul	B12 (Cobalamin)injections (vitamin that impacts fatty and amino acid metabolism)		
Libertas ABDEK	Coenzyme Q		
	Creatine monohydrate(treatment of impaired production of creatine)		
	Carnitine		
	Folic Acid		

	Hydroxocobalamin (B12 _a) (tx of fatty acid disorders)		
	Levocarnitine		
	Pyridoxine (B6) (regulation of the balance of amino acids)		
	Riboflavin		
	Thiamine(B1)(metabolism of glucose)		
AMINO ACID SUPPLEMENTATION:			
Alanine	L-Alanine	Phenylalanine	L-Phenylalanine
Arginine*	L-Arginine*	Proline*	L-Proline*
Asparagine	L-Asparagine	Serine*	L-Serine*
Aspartic acid	L-Aspartic acid	Threonine	L-Threonine
Cystine*	L-Cystine*	Tryptophan	L-Tryptophan
Glutamic acid	L-Glutamic acid	Tyrosine*	L-Tyrosine*
Glutamine*	L-Glutamine*	Valine	L-Valine

*-conditional amino acids, usually not essential except in times of illness or stress

Good morning Chairman Weisz and members of the House Human Services Committee. My name is Kimberly Hruby and I am the Director for the Division of Special Health Services in the North Dakota Department of Health. I do not have testimony for Senate Bill 2224, relating to medical assistance coverage of metabolic supplements, but want to let you know I am available virtually to answer questions, if needed. Thank you.

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

SB 2224
3/8/2021 350 PM

Relating to medical assistance coverage of metabolic supplements

Chairman Weisz opened the committee meeting at 3:51 p.m.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	A
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- SB 2224 Committee Action

Rep. Gretchen Dobervich (3:51) moved Do Pass

Rep. Kathy Skroch (3:52) second

Representatives	Vote
Representative Robin Weisz	Y
Representative Karen M. Rohr	N
Representative Mike Beltz	N
Representative Chuck Damschen	Y
Representative Bill Devlin	N
Representative Gretchen Dobervich	Y
Representative Clayton Fegley	N
Representative Dwight Kiefert	Y
Representative Todd Porter	Y
Representative Matthew Ruby	A
Representative Mary Schneider	Y
Representative Kathy Skroch	Y
Representative Bill Tveit	N
Representative Greg Westlind	Y

House Human Services Committee

SB 2224

03/08/2021 3:50 PM

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Motion Carried Do Pass 8-5-1

Bill Carrier: Rep. Gretchen Dobervich

Chairman Weisz adjourned at 3:54 p.m.

Tamara Krause, Committee Clerk

REPORT OF STANDING COMMITTEE

SB 2224, as engrossed: Human Services Committee (Rep. Weisz, Chairman)
recommends **DO PASS** (8 YEAS, 5 NAYS, 1 ABSENT AND NOT VOTING).
Engrossed SB 2224 was placed on the Fourteenth order on the calendar.