Wisconsin State Senate
24th Senate District

Serving Wood, Portage, Adams,
Waushara, Monroe, and Jackson

PATRICK TESTIN
STATE SENATOR

DATE: May 26, 2021

RE: **Testimony on Senate Bill 259**

TO: The Senate Committee on Insurance, Licensing and Forestry

FROM: Senator Patrick Testin

Thank you Chairperson Felzkowski and Insurance, Licensing and Forestry Committee members for hearing my testimony in support of Senate Bill 259 (SB 259).

Genetic counselors are healthcare professionals who have a specialized graduate degree, academic training and experience in both medical genetics and counseling. They work with physicians or independently to provide genetic services to families. Genetic counselors assess risk for a genetic condition, and then educate patients about available options. Genetic counselors are able increase quality of care and cost effectiveness.

Currently, Wisconsin has no legal standard to regulate who can represent themselves as genetic counselors. Licensure would be a way for the state to ensure that genetic counselors have appropriate education, training and certification. It would also allow the state to prevent unqualified individuals from practicing as genetic counselors, or suspend or revoke the license of those who cause harm.

This bill, Senate Bill 259, would allow for the licensing of genetic counselors, and the regulation of their practice. It has the support of the primary group it would license, the Wisconsin Genetic Counselors Association, and several of the health care associations they work with. It will also ensure patients have peace of mind that the counselor working with them has the proper education, training and is certified to practice.

I appreciate you hearing my testimony and I hope you will join me in supporting this bill.

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DAVID STEFFEN

STATE REPRESENTATIVE • 4TH ASSEMBLY DISTRICT

Chair Felzkowski and Committee on Insurance, Licensing, and Forestry Members,

Thank you for holding a public hearing on SB 259 relating to the regulation and licensure of genetic counselors, creating a genetic counselors affiliated credentialing board, providing an exemption from emergency rule procedures, granting rule-making authority, and providing a penalty.

The United States is the world leader in providing genetic counseling services to individuals and families who are at risk of or suffering from genetic disorders. These advisory services are critical in the medical field, and are performed by highly-skilled, post-graduate scientists with a degree in Genetic Counseling. This growing group of medical professionals are employed throughout university medical centers, private and public hospitals, diagnostic laboratories, and physicians' offices.

Currently in Wisconsin, there is no licensure requirement for those practicing genetic counseling. As it is a growing practice, we believe Wisconsin should join the other 29 states that have implemented genetic counseling licensure. By doing so, patients, counselor employing facilities and the government can be comfortable that the individuals providing these critical services are appropriately and fully trained in their profession.

Under this bill, genetic counselors are added in the definition of "health care provider" and a person who practices genetic counseling is required to be licensed by a seven-member genetic counselors affiliated credentialing board, created by the bill. In addition, this bill requires the board to promulgate rules that define the standards of practice of genetic counseling and permits the board to define the scope of practice of genetic counseling.

This proposal is supported by the Wisconsin Medical Society and the Medical College of Wisconsin.

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UWHealth | School of Medicine and Public Health
UNIVERSITY OF WISCONSIN-MADISON

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Senate Committee on Insurance, Licensing and Forestry
Testimony provided by Peter Levonian, Director
Genetic Counseling Services at UW Health
May 26,2021
RE: Support for Senate Bill 259

Chairwoman Felzkowski and members of the committee,

My name is Peter Levonian and I am a board-certified genetic counselor and Director of Genetic Counseling Services at UW Health. Thank you for this opportunity to appear before you today to express our support for Senate Bill 259 related to licensure for genetic counselors.

UW Health and our partners provide genetic counseling to well over 2,000 Wisconsinites each year. We see patients and families across the lifespan from preconception to adult-onset genetic conditions. We have a team of highly trained board-certified genetic counselors who see patients in multiple disciplines including pediatric genetics, oncology, obstetrics, adult and pediatric cardiology, and adult and pediatric neurology. Using both in-person and telehealth methods, we provide exemplary genetic counseling care in a manner that supports patients and families at times of great stress.

I have been a board-certified genetic counselor for over 30 years and 26 years ago, the nine genetic counselors in Wisconsin at the time came together for a meeting to discuss the merits of licensure for genetic counselors so the public would be able to identify who was qualified to help them navigate the complex genetic terrain. As I reflect on that discussion now, it is almost comical how naïve and understated our assessment of "complex" was all those years ago. In fact, it becomes vastly more complex every year and the potential for harm grows correspondingly.

Two years ago, I saw a 36-year-old woman who had just had both breasts and both ovaries removed surgically because a non-genetic counselor/non-MD provider told her that her genetic test results showed that she was at high risk for developing breast and ovarian cancer. She did not have pre-test genetic counseling, nor did she have a genetic counselor review her genetic test results prior to proceeding with these irreversible surgeries. Had she had access to a qualified genetic counselor, she would have learned that her "mutation" was not a mutation at all, but rather a subtle change in her DNA code that was likely just a harmless difference from one human being to the next. You may ask, "Why didn't she seek a second opinion?" Unfortunately, she trusted the individual who gave her incorrect counsel because she had no way of identifying who was qualified to practice genetic counseling.

We must give patients and families a tool to help identify who is qualified to guide them through significant health care decisions like the patient I reference. The potential harm to the public from inadequately trained (if well-intentioned) individuals is enormous and life-altering.

In my role as director of genetic counseling services at UW Health, it is my job to hire genetic counselors for a variety of clinical roles at the hospital and clinics. Early this month we completed a hire of two new pediatric genetic counselors. Although I am very pleased with the outcome of the recruitment process, the lack of licensure in Wisconsin became an issue for some potential applicants. Two high-value applicants reached out to me privately before applying. They wanted to know the status of genetic counselor licensure in Wisconsin. Upon hearing that genetic counselors are not licensed in our state, they withdrew their interest. Fairly or not, licensure has become a measuring stick of the level of value placed on the profession within a state. I want to

be able to hire the best genetic counselors to serve the patients and families in Wisconsin. I should not be hampered by the lack of licensure.

It is for these reasons that we hope you see fit to support Senate Bill 259. Thank you for your consideration.

School of Medicine
and Public Health
UNIVERSITY OF WISCONSIN–MADISON

Clinical Genetics
Department of Pediatrics

May 24, 2021

Chairwoman Mary Felzkowski
Insurance, Licensing and Forestry Committee

Re: Senate Bill 259

Dear Chairwoman Felzkowski and members of the committee,

I am writing this letter of support for the Senate Bill 259 for genetic counselor licensure. As a physician specializing in clinical genetics and pediatrics for 25 years, and in my present position as Division Chief of Genetics and Metabolism, Professor of Pediatrics in the School of Medicine and Public Health at the University of Wisconsin in Madison, I can attest to the invaluable and critical role of the genetic counselor in the evaluation, management and counseling of both children and adults seeking medical care in all areas of medicine. Recognition and validation of the genetic counselors' training, accreditation and expertise with licensure is vital to their practice, as it is to any other health care provider.

During my career in genetics at University of Iowa School of Medicine, Children's National Medical Center, in Washington, DC, and the National Human Genome Research Institute, National Institutes of Health, I have relied upon and worked closely with genetic counselors, who are an integral part of the medical care team. It goes without saying that in any clinical, research or academic institution delivering genetic services or testing, there are genetic counselors practicing, either independently or as part of a team with medical geneticists (like myself), or other medical subspecialists in hematology/oncology, obstetrics/gynecology, cardiology, and many others. There are multiple studies demonstrating that genetic counselors fill a tremendous and growing need for genetic services, and are able to correctly select genetic testing resulting in health care cost savings. Genetic counselors are master's trained health care professionals who provide consumers with information, education, counseling, advocacy and emotional support for medical conditions that are either entirely or partially determined by genetic factors. Genetic counseling training programs provide their graduates with rigorous training in science, counseling, and clinical skills. The training criteria are set by a national accreditation body. Following graduation from an accredited institution, certification is achieved through successful completion of a national certification exam.

Each medical specialist is required to be licensed to verify their competency; genetic counseling should not be the exception. State licensure is the last step in this process to ensure that providers of genetic counseling services have appropriate training and credentials to keep the citizens of Wisconsin safe. Currently, there is no legal specification in Wisconsin for who may use the title of genetic counselor or practice genetic counseling. Licensure for genetic

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counselors is an important mechanism by which consumers of genetic counseling services can identify appropriately qualified providers.

For all the reasons that I have outlined, please acknowledge and join me and other health care providers of all medical specialties, especially in genetics, in supporting this bill for genetic counselor licensure.

Sincerely,

Kim M. Keppler-Noreuil, MD
Professor of Pediatrics
Division Chief of Genetics & Metabolism
University of Wisconsin School of Medicine and Public Health

RE: Support for Senate Bill 259

Chairwoman Felzkowski and members of the committee,

Licensure allows genetic counselors to practice at the top of their competency (education and training). Healthcare delivery in our state and nationally is based on regulation. The absence of licensure for genetic counselors holds back their ability to become fully integrated into the healthcare system as hospitals and practices utilize their services conservatively due to the lack of legal clarity in what a genetic counselor is able to do. Licensure provides the standardized legal framework for which concrete decisions can be made and then holds those licensed individuals to maintain their certifications and training to a defined set of standards. It also provides a mechanism to sanction individuals when they are providing sub-standard care.

I also want to highlight a very important difference about the licensure of Certified Genetic Counselors (CGC) compared to other types of licensed professions in our state. Although licensure will require that a genetic counselor be board certified, if they are to call themselves a certified genetic counselor, the license won't limit who can come into the profession as it does for other professions – it is limited by who can go to an accredited training program and then sit for the board certification exam. There are a finite number of spots for training, (and Wisconsin has two of only 51 Genetic Counseling Programs), so that is the limiting factor, licensure will not be limiting who can enter the profession in Wisconsin. **However, *without licensure* in Wisconsin, it is limiting Genetic Counselors from practicing independently and improving access to these health care professionals in all areas of Wisconsin. It is virtually impossible to open a private practice without licensure in our state as the health plans will not recognize us as a health care provider, thus limiting the private market for our profession, and limiting our ability to expand our services in the state, and attract highly qualified business minded CGCs from establishing practice in our state. This limits our ability to expand our reach to all of our residents, and also leaves us limited options on where we can be employed. We want to retain our talent and encourage those who come to the training programs here, to stay.**

A good example of this barrier is hospital credentialing. Most hospital bylaws require state licensure in order to credential a practitioner as an independent provider. Without licensure, a genetic counselor has to work under the supervision of physician in these instances. This not only creates barriers, it is inefficient, as generally, the certified genetic counselor will have more knowledge about genetic services than the supervising physician, this also creates added liability for that physician who has no expertise in the field they are "supervising". Medical geneticists would be the exception, as well as physicians who have taken the time to really practice genomic medicine, but there are *far fewer* of these physicians in the United States than genetic counselors.

Another example of this, is data from Ohio State University Medical Center (OSU), a medical facility that has a licensure bylaw requirement. Prior to licensure OSU had one cancer genetics clinic that was seeing an average of six patients per week. The genetic counselor had to coordinate schedules with the patient and supervising physician, creating many barriers to patient care. Post licensure, genetic counselors were credentialed to practice independently, and they were able to go from seeing six patients per week to seeing sixteen patients. In addition, they opened an additional two clinics that each saw sixteen patients per week. Licensure improved access dramatically.

It is also important to note, that genetic counselors collaborate within a medical team. Licensure, however, provides maximum flexibility in how their services are delivered. Wisconsin will be at a distinct

disadvantage in attracting new and retaining genetic counselors as Iowa, Minnesota, Illinois and Michigan all license genetic counselors as independent practitioners consistent with the additional states that license genetic counselors.

Most importantly, licensure is the appropriate state regulatory regime to protect patients from potential harms **caused by genetic counselors**, much as other types of licensure protect patients from errors by other types of health care providers. Currently, *anyone could call themselves a genetic counselor* and, in the event of malpractice, the patient had no legal recourse for redress. Licensure ensures the proper remedial actions are taken to prevent and minimize errors to protect patients from harm. Without licensure there is no mechanism for addressing these specific medical errors.

Examples of Cases Involving Harm by Genetic Counselors

All medical professionals are capable of error and many fields have a licensure system in place to address such errors. Licensure ensures the proper remedial actions are taken to prevent and minimize errors to protect patients from harm. Without licensure there is no mechanism for addressing these specific medical errors.

- The hospital employing a genetic counselor was sued by patients who claimed inadequate pre-test genetic counseling. During the procedural consent process for a diagnostic prenatal procedure, an unlicensed genetic counselor reportedly did not inform a pregnant patient of the risks of limb defects. The baby was born with a transverse limb defect.
- 42 S.W.3d 16 (Missouri. 2001): The parents of a son born with spondyloepiphyseal dysplasia tarda, "SEDT", took their medical team, including a genetic counselor, to court on the grounds of fraudulent misrepresentation. The wife had two relatives with SEDT and the couple wanted to know the risk to their pregnancy so they could prepare. The parents claim the report that they received assessed their risk lower than their actual risk. They conceived a child based on their risk assessment with the genetic counselor.
- A genetic counselor was the defendant in a case that resulted in an $800,000 settlement. The patient had undergone genetic testing for a hereditary cancer syndrome. The genetic counselor failed to recommend additional follow-up testing for the patient, and the patient subsequently developed breast cancer.

Examples of Cases of Harm Involving the Absence of a Genetic Counselor

When genetic counselors are not utilized or are unavailable to our state residents, the substitution effect can cause great harm to patients via incomplete risk assessments, improper test utilization, and inaccurate result interpretations.

- A woman was diagnosed with breast cancer after a physician informed her that her paternal family history of breast cancer was not relevant. She was later found to carry a mutation in a breast cancer-causing gene.
- A woman's physician declined to refer her for genetic counseling multiple times after she was diagnosed with early-onset breast cancer, despite her family history and ethnic risk factors. She was later found to have a BRCA1 mutation and died of ovarian cancer.

• A woman with a family history of Duchenne muscular dystrophy (DMD) who was *never offered* genetic counseling or diagnostic procedures terminated her pregnancy after assuming her male fetus was affected with DMD.

Examples of Cases of Financial Harm

Inappropriate and unnecessary genetic testing contributes to increasing societal healthcare costs. Recent evidence-based research demonstrates that genetic counselors provide a net savings when they are involved in the genetic testing process. Examples include:

• Priority Health, a private insurance company in Michigan, mandated the use of genetic counselors prior to the approval of certain genetic tests. This program prevented over $10 million worth of inappropriate tests and a net savings of $7.2 million.
• The Department of Veterans Affairs Genomic Medicine Service recently conducted a cursory chart review of their first 100 genetic referrals, in which testing was ordered for 19 patients by a practitioner other than a licensed genetic counselor. These tests would have cost taxpayers $109,369 and after review by a genetic counselor, only $18,345 of genetic tests were determined to be medically indicated for a cost savings of $91,024.
• Licensed genetic counselors at ARUP Laboratories performed a clinical review of all genetic tests over an 11-month period. They cancelled or changed inappropriately ordered genetic tests for an average cost savings of $36,500 per month, representing approximately 30 percent of all complex genetic tests ordered.

Genetic services certainly can cause harm when they are delivered by those not qualified. The science behind genetics is very complicated and exciting innovation is occurring daily; even those trained in genetics make mistakes. Licensure can protect patients from mistakes. From our experience with the current employment trends for genetic counselors, enacting licensure would make Wisconsin more competitive in attracting genetic counselors to the state.

Jessica Grzybowski, MS, CGC
Chair, WIGCA Social Policy Committee
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May 25, 2021

Testimony to Support Licensure for Genetic Counseling (AB255, SB259)
Christina Zaleski, MS, CGC

Chairman Sortwell/Chairwoman Felzkowski and distinguished members; I am Christina Zaleski. I'm a certified genetic counselor from Marshfield, WI. I am currently the Director of Genetic Counseling & Client Services at PreventionGenetics. I previously worked in both research and clinical settings. I am also past president of the WI Genetic Counseling Association. I am here today to represent our profession from my family's perspective to share a story of how this bill can protect patients.

At the age of 39, my grandma developed an enlarged, ballooned heart, referred to in the medical world as cardiomyopathy. In her late 50's, she was the oldest heart transplant recipient in WI. I was 13 at the time. Little did I know that her cardiologist at the time who inspired an interest in medicine and let me spend time shadowing him in clinic showing me the tools he used to biopsy my grandma's new heart to check to make sure she wasn't rejecting it, would eventually be the same cardiologist that would later trust me as a Certified Genetic Counselor to use the power of genetic medicine to save my dad's life.

At the time of grandma's transplant, she was told that a new heart may give her 5 bonus years to live. 26 years later she died of "old age". In college and graduate school studying genetics I learned that my grandma's heart problem might be inherited. Early in my career as a genetic counselor I worked hard to learn and document our full family history- to better understand if my family history would impact the chance of others having related heart issues. In talking with family and pulling together our family history I uncovered that my grandma's brother died in his sleep in his mid-60s and his autopsy showed a ballooned heart just like grandma's. Grandma assured me their hearts were caused by a childhood infection- scarlet fever I think is what she said, but as a genetic counselor having had specific training during graduate school, I was suspicious that there could be more to the story.

Two siblings with a relatively uncommon heart condition was enough for me to work with grandma's cardiologist to order genetic testing. While grandma was in good shape because she was doing well post transplant, I was concerned about my dad & his 5 siblings, not to mention 16 grandchildren and 24 great grandchildren that could be at risk for either an enlarged heart or life threatening related heart rhythm problems. Nearly everyone in the family are WI residents. Genetic testing performed over 16 years ago was negative. No genetic cause was identified. If this was most people and their encounter with genetic testing, this may have been the end of the story.

As a patient, I was relieved, but as a genetic counselor I understood the limitations of technology and the importance of staying up to date related to advances in genetics that could help my family. I banked grandma's DNA as a Christmas gift one year & grandma listed me as the representative who could have access to it if we ever needed to go back to it after her death. I know from my day to day work that most people are unaware of the value of DNA banking, but luckily I knew this was an option because of my training.

Fast forward our story several years. A few months after grandma's death about 5 years ago, my dad had a cardiac situation. There were concerns that he might be having a heart attack, so as you can imagine, this earned him a big cardiac workup. There were also concerns on whether he might have a heart rhythm issue that caused the problem. Our cardiologist was not convinced it was related to Grandma's condition, but there were some very subtle heart rhythm concerns including strings of irregular heartbeats. As a GC, I explained to my dad and his care team that advances in technology have discovered new genes associated with cardiomyopathy. From my training and continued education in genetics I knew that these genes can cause a ballooned heart, but they can also cause serious, life threatening rhythm problems if left untreated. As many as 1 in 500 adults may have this condition, so knowing our family history and working alongside the cardiologist was critical.

Ultimately dad's cardiologist (who, as a colleague often leaned on me to help obtain family histories for his other patients, and the same cardiologist that I shadowed as a 13 year old when he took care of my grandma) consulted with a medical geneticist and my dad underwent genetic testing. We captured some of the newer genes that had been discovered after my grandma's testing. Together we made a good team to make sure my dad was getting the best care.

A complicated genetic change was found in a gene called *TTN*. The results were uncertain, but fortunately I had specialized knowledge of diagnostic genetic testing and knew some things we could do to help clarify it.

I suggested to my dad's care team that we go back and pull the banked DNA from my deceased grandma to compare her *TTN* gene to my dad's. They were thrilled that we had preserved that sample to test. Grandma carried the same genetic finding. Dad's cardiologist hesitated to act on this because of risks of doing more procedures, but together we decided that genetic testing results suggested that he may benefit from doing a more invasive test on his heart. My dad underwent a procedure where he was unconscious but his heart was stressed to see if a life threatening arrhythmia could be induced. It was a controlled environment that would tell us if he might benefit from having a pacemaker and an implantable defibrillator in his chest which would restart his heart if needed. The procedure showed that his heart was inducible, and he did earn himself a pacemaker & defibrillator that day. I can still remember the look on the cardiologist's face when he came out of the procedure to tell us the news- it was almost disbelief. He also told me that he never would have guessed this outcome and had it not been for his genetic test results and for the conversations we had that he never would have considered performing this procedure.

Our cardiologist told me he gave my dad an insurance policy in his chest that hopefully he would never need. Two years later that ICD saved my dad's life as it kicked in during his sleep and shocked him into a normal rhythm. He actually never even woke up when it went off. Mom remembers a big jolt in their bed, and when his recording was turned into the clinic for routine checking, it showed that the device did kick in and the "big jolt" my mom remembered then made a lot more sense. My dad would have died in his sleep that night had he not had that "insurance policy" inserted in his chest thanks to his genetic test results and the collaboration of his cardiologist with a genetic counselor.

Genetic counselors have advanced training in medical genetics and counseling to interpret genetic test results and to guide and support patients and healthcare providers seeking more information. Genetic counselors help patients make informed decisions with healthcare. From gathering family history, to understanding the role for genetic testing, to understanding limitations of technology and then going back to re-address this with advancements, to later on helping the rest of a family understand the implications that all of this could have on their own health. This is the value that a genetic counselor brings to the healthcare team.

My personal story is an example of how GCs can collaborate (without infringing) on other subspecialties. I am grateful for the support from our cardiologist who was open to the power of genetic medicine and what I could contribute as a certified genetic counselor. As a profession, genetic counselors work closely with many specialties, many of which have also signed on in support of this bill. Our family cardiologist has also submitted a letter of support for this bill last spring.

I went into genetics to make a difference for patients. I am also grateful that my own genetic training as a GC may have actually saved my dad's life.

I hope that you will work together to enact genetic counseling licensure to ensure that the citizens of WI receive quality genetic counseling services and help patients. We need licensure to increase access to these services for all of the citizens of Wisconsin. I hate to think of what my dad's outcome would have been had he not had access to a certified genetic counselor. Thank you for your time today.

Testimony for GC Licensure Bill
Gina Londre, MS, CGC
May 24th, 2021

To the distinguished members of Assembly and Senate,

My name is Gina Londre. I am a certified genetic counselor practicing in Wisconsin. With the timing of the GC Licensure Bill (AB 255 and SB 259) public hearings, I would have felt remiss in not sharing my personal and professional testimony, as my family's story highlights how access to genetic counseling is not only critical for patient safety but also for appropriate family counseling.

This Monday, May 24th, marks 5 years since my nephew, Donovan, passed away. He was an unmatched bright spot in this world, with a laugh and big toothy grin that even the grumpiest of souls couldn't resist. He was loved by all who had the pleasure of knowing him. He passed far too young at the age of 14, ultimately succumbing to the genetic disorder, *MECP2* Duplication syndrome, that threatened to take his life many times prior. He resided in WI his entire life.

It was only a year and a half before his death we had learned the name of this disorder. However, unbeknownst to us, this diagnosis had already been identified and sitting, unshared, in his medical record for over 3 years. The testing had been ordered during one of his ICU stays in the summer of 2011 by a well-intended non-genetics specialist, among the myriad of tests performed while a patient is critically ill in the ICU. My sister did not know or did not remember this testing had been ordered, and no results were ever shared during or after his ICU stay. It wasn't until 3 years later (Fall 2014) when, as a genetic counselor, I prompted my sister to consider a genetic evaluation. I was concerned that with a diagnosis, we might better understand what to expect and how to care for Donovan. I was also concerned about recurrence risks for myself, but also other family members as there were other affected boys in our family. I accompanied my sister and nephew to their initial appointment in Genetics expecting various tests to be considered. It was at that visit a genetic counselor disclosed the results to us. What was originally a pretesting appointment turned into a results disclosure. Our genetic counselor had performed a thorough record review in preparation for our visit as they were trained to do, and they were both empathic and informative, guiding us as we rode the roller coaster of unexpected emotions: surprise, sadness, relief, fear.

While this result sadly did not ultimately change the trajectory of his disease course and medical care, it gave us a name. It gave us an idea of what was to come. It gave us an option to seek support from others with the same diagnosis; I think it was within a matter of days my sister and others in our family had joined a Facebook support group for families affected by the same disorder. I am sad that my sister (and others) were robbed of the opportunity for direct connection and support sooner. I strongly believe that had a genetic counselor been involved from the outset, those results would have landed in our laps promptly upon completion. While I was not thrilled to learn that my nephew had an x-linked condition, where women in the family could be carriers and at-risk to have affected sons, the genetic counseling for myself and the rest of the family helped us understand the recurrence risks and ultimately helped with family planning so that other at-risk women in the family could consider ways to decrease risk, including options like preimplantation genetic testing, adoption, and egg donation.

As a patient, it makes me angry that had I not gotten involved and understood the value of genetic counseling, my family would not have learned of Donovan's diagnosis and found the support that, 5 years after Donovan's death, continues to bring my sister comfort. Had my family not had appropriate genetic counseling to understand recurrence risks, we would not have had the benefit of making informed reproductive decisions, and there could quite possibly be other boys suffering from this fatal genetic condition.

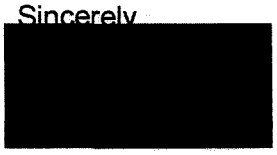
Passing this licensure bill will increase access to genetic counselors by making them more identifiable and searchable among licensed healthcare professionals, which in turn should increase patient access to high quality genetic services. As a genetic counselor, it makes me sad and scared that lack of access to qualified genetic counselors, whose licensure should be aligned with other allied-health practitioners, will compromise patient care.

Let's consider patient-protection... While my family could have easily pursued legal recourse against the well-intended, licensed physician who ordered testing and failed to disclose results, had a genetic counselor done the same, would there have been the same opportunity for holding them accountable without licensure? And even moreso, what if genetic testing results would have changed his medical management, thereby improving his quality of life or potentially preventing his death? Licensure will define the genetic counselor scope of work and lay the foundation to ensure those who claim to be genetic counselors are appropriately trained and held accountable to provide proper care.

By now, it's probably no surprise that one of the biggest driving forces in my career path as a genetic counselor was my nephew... along with my brother, my cousin, and other affected male relatives that came before them. All have long passed, but I hope to honor them continuously and ensure future patient safety while having access to high quality, appropriate care provided by licensed genetic counselors. I want hospitals and laboratories in WI to be competitive and attract and retain talented professionals to offer support and care for our residents. Licensure will help get us there.

I sincerely thank you for your consideration of this licensure bill. Twenty-Nine other states (including all our neighboring states) offer licensure for genetic counselors. I hope Wisconsin is next so that residents in our state benefit from the protections and access that it will offer.

Sincerely,



Gina Londre, MS, CGC
Genetic Counselor

Aurora Cancer Care®

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April 20, 2021

To Whom it May Concern:

I am a surgical oncologist who is Vice President of the Cancer Service Line for Aurora Health Care which is now part of AdvocateAurora Health. As such, my team oversees the care of over 8000 new cancer patients yearly in the state of Wisconsin. Genetic Counselors are becoming an increasingly important team member in the care of these patients and as such we strongly believe they should be licensed professionals. We are therefore asking you to support Assembly bill AB 255 Introduced by Representatives Steffen, Rozar, Brostoff, Billings, Cabral-Guevara, Dittrich, Duchow, Goyke, Kitchens, Kuglitsch, Skowronski, Tittl and Wichgers; cosponsored by Senators Testin, Darling, Erpenbach, Johnson, Larson, Pfaff and Wirch.

This bill was referred to your Committee on Regulatory Licensing Reform on 4/8/2021.

Genetic Counselors are unique in that in order to protect the safety of patients, they need special training and certification, and with that, the licensure to be recognized as a trained member of the complex healthcare team. They interpret genetic testing results and advise on hereditary conditions. This is a type of specialization that requires oversight via licensure to protect our community and provide access to quality care.

Currently in Wisconsin, there is no licensure requirement for those practicing genetic counseling. As it is a growing practice, we believe Wisconsin should join the other 27 states that have implemented genetic counseling licensure. By doing so, patients, counselor employing facilities and the government can be comfortable that the individuals providing these critical services are appropriately and fully trained in their profession.

I respectfully request that you add this bill to your committee agenda as soon as possible, this is an important bill.

Best regards,

James L. Weese, MD, FACS
Adjunct Clinical Professor of Surgery
University of Wisconsin, School of Medicine and Public Health.
Vice President, Aurora Cancer Care
3000 W. Montana Street
Milwaukee, WI 53215

MEDICAL COLLEGE OF WISCONSIN

TO: Honorable Members of the Senate Committee on Insurance, Licensing and Forestry

FROM: Kendra Eaves, MS, CGC
Manager, Genetic Counseling
Medical College of Wisconsin

DATE: May 26, 2021

RE: Please Support Senate Bill 259: The Regulation and Licensure of Genetic Counselors

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The Medical College of Wisconsin (MCW) respectfully requests your support for Senate Bill 259 (SB 259), legislation to create licensure and regulation for genetic counselors. Genetic counselors are healthcare professionals specializing in medical genetics and counseling. Currently in Wisconsin, there is no licensure requirement for those practicing genetic counseling. As a rapidly growing area of care, MCW believes Wisconsin should align our state's licensure laws with the 29 other states which have already enacted licensure for these healthcare practitioners. By doing so, patients may rest assured that these critical services are being delivered appropriately and with a high-level standard of care.

MCW currently employs 21 genetic counselors, who see over 5,000 patients annually at Children's Wisconsin and Froedtert Health clinics. MCW is also developing a Master of Science graduate program to train the next generation of genetic counselors in Wisconsin. As personalized and precision medicine becomes more prominent and critical for patient outcomes, MCW anticipates a dramatic increase in the need for genetic counselors within nearly all areas of medicine.

Genetic counselors enhance the physician-led care team by investing significant time and resources dialoging and assisting patients and their loved-ones. Key services provided include:

- Discussing and analyzing medical history and family history
- Explaining genetics, inheritance, and specific conditions in an easily understandable manner
- Reviewing testing options, ordering genetic tests as appropriate and personalized interpretation of genetic test results
- Providing psychosocial and supportive counseling

Genetic counselors hold Master's degrees in Genetics or Genetic Counseling, and are certified by the American Board of Genetic Counseling. Approximately 100 genetic counselors with this advanced training are currently practicing in Wisconsin. I want to highlight the importance of the existing national accreditation of genetic counseling training programs through the Accreditation Council for Genetic Counseling. Certified genetic counselors graduate from accredited training programs which ensure quality and educational standards are met for the profession. The genetic counselor Practice Based Competencies provide the guidance for the training of genetic counselors and an assessment for maintenance of competency of practicing genetic counselors. The competencies are categorized in the following domains: (I) Genetics Expertise and Analysis; (II) Interpersonal, Psychosocial and Counseling Skills; (III) Education; and (IV) Professional Development & Practice.

SB 259 will protect the public, ensuring there is a legal standard for those representing themselves as genetic counselors, while also ensuring individuals and families receive the highest-quality services. The legislation will also provide the public with a means to identify whether a provider is a licensed and qualified genetic counselor and help ensure broad public access to these services throughout Wisconsin.

Finally, this legislation does not preclude other practitioners from providing genetic counseling if these activities are within their scope of practice and will align genetic counseling with licensure and regulation of other allied-health practitioners. Thank you for your time and attention.

MCW respectfully requests your support for SB 259. If you have any questions or need additional information following the conclusion of today's public hearing, please do not hesitate to contact Nathan Berken, MCW's Director of Government Relations, at 414.955.8588, or via email at nberken@mcw.edu.

Marshfield Clinic
HEALTH SYSTEM

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800-782-8581
Fax 715-387-5240

1/28/2020

Dear Chairperson, Vice Chairperson and distinguished Members,

My name is Humberto Vidaillet. I am a medical doctor board certified in internal medicine, cardiovascular disease and clinical cardiac electrophysiology. As a cardiologist, I support Senate Bill 620, which would provide licensure for genetic counselors in Wisconsin. Christina Zaleski will provide you with testimony that I wholeheartedly support.

Genetic counselors play a critical role within my practice and provide information and support to individuals and families affected by, and concerned about, risk of genetic disorders.

The availability of genetic and genomic testing services is rapidly growing. Genetic counselors are ideally suited to work with cardiologists to deliver high quality, up-to-date genomics services and to ensure that patients using these services are adequately informed. Genetic counselors are vital collaborators in my practice.

Genetic counselors' expertise enables them to provide services that are cost-effective by ordering the right test for the right person. Many healthcare providers, who are not trained in genetics, request unnecessary or incorrect tests, which significantly increases healthcare costs.

Clinicians and patients need to know that the genetic counselors that they work with are adequately trained and up-to-date on genomic information.

As the field of medical genetics grows, so too does the need to provide the citizens of Wisconsin with accurate information regarding their genetic conditions, genetic risks, and results of genetic tests. No mechanism currently exists to ensure that the individual providing genetic counseling to citizens of Wisconsin is qualified to do so. In a climate where direct-to-consumer genetic testing is available and the complexity of genomic tests is increasing, the citizens of Wisconsin need to have access to professionals who have been deemed qualified by the state.

I hope that the committee will work with Wisconsin Genetic Counselor Association to enact genetic counseling licensure to ensure that the citizens of Wisconsin receive quality genetic counselor services. I thank the Chairman and this committee for your attention to this important issue.

Sincerely,

Humberto J. Vidaillet Jr. MD, FACP, FACC, FHRS
Cardiologist, Electrophysiologist

February 2, 2021

To Whom it May Concern:

I am writing as a medical geneticist who has practiced in Wisconsin for over 20 years, and in Iowa for 20 years prior to this. I am currently employed as a medical geneticist in the Department of Pediatrics, University of Wisconsin School of Medicine and Public Health. During my long career I have worked extensively, side-by-side with knowledgeable genetic counselors who have played essential roles in my medical genetics practice and substantially assisted me in caring for pediatric and adult patients with genetic disorders. Physicians practicing in medical genetics face an almost dizzying, ever-changing landscape of genetic tests across a wide range of conditions, including oncology, neurology, cardiology, and rare diseases. I believe strongly that utilizing the full spectrum of options for genetic testing to benefit patients requires a multi-disciplinary approach to health care delivery which relies heavily on the skills, knowledge, and clinical and scientific acumen of our genetic counselor colleagues.

As medical geneticists, we support the critical role of genetic counselors in keeping up with the innovations in genetic testing that are improving patient care and outcomes. Genetic counselors have the specialized training and knowledge necessary to evaluate and distinguish among the dramatically increasing number of genetic test options. Genetic counselors synthesize medical information, and in conjunction with the physician's evaluation and diagnosis, ensure that the most appropriate genetic test is provided based on each patient's unique medical characteristics. Genetic counselors offer time-intensive services to patients, explaining genetic disease risks and options for genetic testing, as well as interpreting genetic test results. They ultimately help us to provide optimal and individualized genetic and medical care and services to our patients.

I strongly support the current WI Senate Bill SB-259 and WI Assembly Bill AB 255, since this legislation would allow for licensure of genetic counselors in Wisconsin. I believe this is a critically important step in the development and advancement of up-to-date genetic services in our state. Our country is facing a critical shortage of medical providers, particularly as the nation's population ages. These shortages are occurring even more rapidly in the field of medical genetics, as demonstrated by a 2019 study in which ACMG researchers identified a shortage of medical genetics providers and barriers in patient access to care, particularly for vulnerable, rural, and underserved populations. Allowing genetic counselors to be recognized as licensed specialists would allow them to continue practicing in areas of need while maintaining their high standards of training, education, and care.

Genetic counselors are embedded in clinics specializing in oncology, cardiology, neurology, hematology, and ophthalmology services, and many more, throughout the health care system. In these other specialized care sites, genetic counselors provide important services to physicians from a wide range of disciplines other than medical genetics, helping to enhance and optimize patient care. During this particularly stressful and dangerous COVID-19 pandemic, transitioning to providing telemedicine genetic services with genetic counselors for Wisconsin patients has become very difficult due to billing issues caused by of lack of licensure. Therefore, it is even more critical for us to recognize genetic counselors as licensed healthcare professionals to allow them to continue their great work in a virtual platform as well as in person in healthcare clinics throughout Wisconsin. I strongly and unequivocally support these Wisconsin bills to provide licensure for genetic counselors.

If you have any further questions regarding my support, please feel free to contact me at **wrhead@uwisc.edu.**

Sincerely,

William J. Rhead, MD, PhD
Adjunct Clinical Instructor of Pediatrics/Genetics,
University of Wisconsin School of Medicine and Public Health
Home address: 12605 W. Grove Terrace, Elm Grove, Wisconsin, 53122
CELL PHONE: 414-550-2011

Re: Wisconsin Senate Bill 259

Relating to: the regulation and licensure of genetic counselors, creating a genetic counselors affiliated credentialing board, providing an exemption from emergency rule procedures, granting rule-making authority, and providing a penalty

Dear Chairwoman Felzkowski and Members of the Committee,

I am writing this letter on my own behalf in support of the efforts for the establishment of genetic counselor licensure requirements and appreciate your willingness to hear the attendees testimonies as it relates to this topic. In my professional capacity, I lead the pediatric genetics services coordinated through the Medical College of Wisconsin and Children's Wisconsin. My personal views do not reflect those of my employer.

I have been in clinical practice for 20 years and have valued the professional partnership between genetic counselors and genetics medical providers. With the ever-changing arena of genetic testing and implementation of treatments targeted at genetic disorders, it is imperative that genetic counselors who practice either in partnership or independently of a medical geneticist have the professional responsibility of ensuring best practice and optimal patient outcomes through correct interpretation of genetic test results and appropriate referral for current standard of care therapy or management recommendations. I have seen firsthand the limitation that lack of licensure has imposed on my ability to develop genetic services and this is merely scratching the surface of how the lack of licensure impacts wider implementation of genetics services across the state. This is particularly relevant as it relates to providing services geographically closer to the citizens of Wisconsin and enabling access to these services for all of the population.

I feel strongly that licensure for genetic counselors will improve access to genetic services and enable genetic counselors to be recognized in their important roles as advanced practice providers within the field of genomic medicine.

Yours sincerely,

Donald Basel, MD FACMG

Contact details: 503-840-8963 , 1905 Derrin Lane Brookfield WI 53045, dbasel@mcw.edu

Great Lakes
Pathologists, S.C.

December 15th, 2017

Great Lakes Pathologists, S.C.
8701 W. Lincoln Avenue
Milwaukee, WI 53227

Great Lakes Pathologists, S.C., supports efforts that will improve access to quality healthcare services, including genetic counseling services, in Wisconsin. We support the Wisconsin Genetic Counselors Association's efforts to secure licensure for genetic counselors in Wisconsin as means towards this end.

The field of medical genetics has experienced tremendous growth in recent years that has impacted virtually all areas of medicine. Correspondingly, the importance of providing quality genetic counseling services is evermore important since consumers are increasingly making healthcare decisions based upon genetic risk factors and results of a variety of genetic tests. The growing complexity of genetic tests and emergence of direct-to-consumer genetic tests further highlights the need for ensuring access to quality genetic counselors.

Genetic counselors are Master's trained health care professionals who provide consumers with information, education, counseling, advocacy and emotional support for medical conditions that are either entirely or partially determined by genetic factors. Licensure for genetic counselors is critical to ensure that providers of genetic counseling services have appropriate training and credentials so that individuals receive proper information and care. Currently, there is no legal specification in Wisconsin for who may use the title of genetic counselor. Licensure for genetic counselors is an important mechanism by which consumers of genetic counseling services can identify appropriately qualified providers.

West Allis Memorial Hospital
8901 West Lincoln Avenue, West Allis, WI 53227
Tel (414) 328-7950 • Fax (414) 328-7998

Great Lakes
Pathologists, S.C.

Please consider championing legislation for genetic counselor licensure.

Sincerely yours,

Krista L. D'Amore MD

Michael H. Whittaker M.D.

MD

MD

MD

Kunle Adesoka MD

Sherri J. Mann, MD
Krista L. D'Amore, MD
Steven D. Dubner, MD
Michael H. Whittaker, MD
Christine A. Wynveen, MD
Adekunle Adesokan, MD
Karin H. Gerdisch, MD

Surgical Pathologists
Great Lakes Pathologists

West Allis Memorial Hospital
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Tel (414) 328-7950 • Fax (414) 328-7998

SSMHealth.

Dean Medical Group
Madison, Wisconsin
deancare.com

December 5, 2017

To Whom it May Concern,

I support efforts that will improve access to quality healthcare services, including genetic counseling services, in Wisconsin. I support the Wisconsin Genetic Counselors Association's efforts to secure licensure for genetic counselors in Wisconsin as means towards this end.

The field of medical genetics has experienced tremendous growth in recent years that has impacted virtually all areas of medicine. Correspondingly, the importance of providing quality genetic counseling services is ever more important since consumers are increasingly making healthcare decisions based upon genetic risk factors and results of a variety of genetic tests. The growing complexity of genetic tests and emergence of direct-to-consumer genetic tests further highlights the need for ensuring access to quality genetic counselors.

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Please consider championing legislation for genetic counselor licensure.

Sincerely yours,

Susan Davidson MD

Susan Davidson, MD
Maternal Fetal Medicine
SSM Health Dean Medical Group

May 26, 2021

To the Honorable Chair Mary Felzkowski, Vice-Chair Rob Stafsholt, and Members of the State Senate Committee on Insurance, Licensing and Forestry:

I support SB-259 (LRB 21-2517/1), relating to the regulation and licensure of genetic counselors in the State of Wisconsin, creating a genetic counselors affiliated credentialing board, providing an exemption from emergency rule procedures, granting rule-making authority, and providing a penalty.

Genetic counselors work as members of a healthcare team, providing information and support to individuals with birth defects, genetic disorders, and to families who may be at risk for a variety of inherited conditions. I am a Genetic Counselor who is board certified by the American Board of Genetic Counseling and living in Racine County. I worked as a clinical genetic counselor at Aurora Health Care, Froedtert and The Medical College of Wisconsin, and ProHealth Care prior to working as a Clinical Genomics Scientist for Invitae, an industry-leading diagnostic laboratory.

It truly is an honor to work with so many families and healthcare teams in Wisconsin, not only providing education about complex genetic concepts and disorders, but also providing counseling and emotional support related to the implications of genetic risk assessments and/or testing. The scope of clinical genetics continues to rapidly expand from traditionally rare genetic disorders now including common conditions, such as cancer, heart disease, autism, and diabetes, which have been shown to have a genetic basis in many families. Working for a diagnostic laboratory in clinical operations related to DNA interpretation and reporting, I understand first hand how critically important it is to be able to understand and communicate genetic information, especially related to personal or familial risk for disease, due to the impact on psychological well-being and potentially life-saving decisions regarding medical management or treatment.

Licensure is the first necessary step toward establishing genetic counselors as allied health professionals. Just as physicians and nurses have both board certification and state licensure, so should genetic counselors. Increased public awareness, coupled with scientific advances in adult disorders and reproductive technologies, have increased the demand for genetic counselors. Genetic counselors are the primary source in Wisconsin to assist patients and their physicians who have questions about the validity of genetic testing, reliability of laboratories providing genetic testing, and the interpretation and implications of genetic test results.

The recent explosion of direct-to-consumer genetic testing truly underscores the need for the public to be able to recognize who is qualified to provide genetic counseling services and to interpret genetic test results. Licensure would protect patients and families from harm upon

receiving incorrect information or inappropriate counseling. Licensure also would allow healthcare providers, particularly those with limited genetic knowledge and psychosocial training, to recognize and refer to licensed genetic counselors.

Thank you for allowing me the opportunity to provide testimony in support of SB-259. I sincerely appreciate your time and attention to this important matter.

Andrea Nagl, MS, CGC
Clinical Genomics Scientist
Invitae Corporation

Aurora Health Care®

750 W. Virginia Street
Milwaukee, WI 53204

www.AuroraHealthCare.org

May 26, 2021

To the distinguished members of the Assembly and Senate,

My name is Deborah Wham. I am a Certified Genetic Counselor and the Manager of the Genomic Medicine Program for Aurora Health Care. I am writing on behalf of Aurora to voice our support for SB 259 and AB 255 – important legislation that will ensure that genetic counselors are appropriately regulated as the health care providers that we are.

For background, Advocate Aurora is among the largest not-for-profit health systems in the United States and the leading employer in the Midwest. We employ more than 70,000 people throughout Wisconsin and northern Illinois, and we see nearly 3 million unique patients per year. Our genetic counseling team consists of 11 genetic counselors here in Wisconsin.

Genetic counselors are healthcare providers with significant training and expertise in molecular biology, medical genetics and psychosocial counseling obtained through a 2-year Master's level program. Most students enter the field from a variety of undergraduate disciplines including biology, genetics, psychology, or public health. There are currently 40 accredited training programs in the United States and this number is growing as more academic centers of excellence institute a focus on precision medicine. The genetic counselor profession is one of the fastest growing in the United States. Since 2006 there has been 88% growth and it continues at a rate of about 7% annually. Currently, there are more than 4,000 genetic counselors in the United States. Locally, the University of Wisconsin has an accredited training program for genetic counselors.

Genetic counselors are part of a health care team providing information and support to individuals and families concerned about risk of genetic disorders. Genetic counselors:

- Collect and interpret family and medical histories,
- Identify individuals and families at risk of genetic conditions
- Explain inheritance and natural history
- Quantify chance of occurrence and recurrence
- Review available testing options
- Discuss management, prevention, and research opportunities
- Serve as patient advocates and refer individuals and families to community or state support services as appropriate

Genetic counselors are employed in a wide range of clinical care, academic, laboratory, research, and biotechnology settings. Within Wisconsin there are 114 genetic counselors, most of whom provide direct patient care in a variety of specialties including but not limited to Oncology, Obstetrics, Pediatrics, Neurology, and Cardiology.

The availability of genetic and genomic testing services is growing rapidly. Approximately 10 new genetic tests come to market each day with varying degrees of validity. Not only are there more tests, the complexity of testing is increasing.

The proposed licensure of genetic counselors in Wisconsin is consistent with the other 29 states that have enacted such laws, including all states bordering Wisconsin. In order to ensure the public is protected and that genetic counselors are able to practice to the full extent of their training in Wisconsin, we are hopeful you will enact SB 620.

Protect the Public

As the practice of genetic counseling grows in prevelance and complexity, minimum standards are needed to protect the public from potential harms that may result from untrained individuals attempting to provide this care. Some examples are:

- Misinformation regarding genetic risk or lack of risk;
- Failing to use CLIA certified laboratories or medical grade genetic tests leading to unnecessary interventions
- Misunderstanding of the implications of genetic information which can lead to:
    - unnecessary medical treatment and/or surgery
    - lack of prevention or disease monitoring strategies
    - irreversible management decisions
    - Avoidable fear, anxiety and guilt
    - Misunderstanding of risk for family members
- Inappropriately undertaking costly unnecessary genetic testing

Genetic counselors, with their specialized training, are ideally suited to work hand-in-hand with physicians and health care providers to ensure the delivery of high quality, up-to-date genomics services and to make sure that the patients utilizing these services are adequately informed. As such, they are key players in appropriately integrating genomics into health care and in avoiding the significant harm that can occur when genetic risk is not identified or when a patient is not properly counseled before genetic testing is done.

In addition, genetic counselors provide services that are cost-effective. They assure tests are utilized appropriately. Many health care providers request unnecessary testing or incorrect tests, which increases the cost of health care. Non-genetics health care professionals have also been demonstrated to underestimate patients' genetic risks because of ineffective family history evaluation. For many genetic conditions, 50% of first degree relatives (siblings, parents, children) of a person with a genetic mutation will also carry a mutation and are at risk to manifest the disease or transmit the mutation. Identifying those who carry a mutation offers the opportunity for preventive screening and treatment, thus lowering the chance of disease manifestations. Moreover, identifying those family members who do not carry a mutation eliminates the need for expensive clinical follow-up.

Improve Access to Genetic Counselors

Many health plans and hospitals require licensure to credential a healthcare practitioner. The absence of licensure impedes the delivery of genetic counseling services in these cases as genetic counselors are not permitted to practice to the full extent of their training. Many states see an increased demand for genetic counselors after licensure has been implemented.

For example, at Ohio State University, licensure allowed credentialing to occur and the oncology department was able to create several genetic counselor clinics that increased the number of patients seen in one clinic from 6 patient slots per week to 16 per week. They hired additional genetic counselors to ensure access was maintained.

Conversely, states without licensure may have a hard time attracting new graduates to the state. These circumstances could place Wisconsin at a disadvantage compared to other states and decrease patient access to the specialized health care services that genetic counselors provide.

In summary, genomics is changing rapidly and genetic counselors are key players in appropriately and effectively integrating genomic applications into health care. Clinicians and patients need to know that the genetic counselors they work with/see are adequately trained and up-to-date on genomic information. Therefore, Aurora Health Care, the Wisconsin Genetic Counselors' Association, and the National Society of Genetic Counselors respectfully request that you support this important legislation. Thank you much for your consideration.

Sincerely,

Master of Genetic Counselor Studies
UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH

5-24-2021

Dear Senate Insurance, Licensing and Forestry Committee Members,

As a Genetic Counselor with 40 years of professional experience, including 20 as director of the graduate genetic counselor training program in the UW School of Medicine and Public health, I am writing to support Senate Bill 259. This bill will improve access to quality genetic counseling services to your constituents, the citizens of Wisconsin.

Genetic Counseling services are an increasingly important component of quality healthcare services including in all specialties and multiple areas of Public Health. Consumers and their providers are making health decisions based upon genetic risk factors and results of a variety of genetic tests. The growing complexity of genetic tests and emergence of direct-to-consumer genetic tests further highlights the need for ensuring access to quality genetic counselors.

Genetic counselors are master's trained health care professionals who provide consumers with information, education, counseling, advocacy and emotional support for medical conditions that are either entirely or partially determined by genetic factors. Genetic counseling training programs provide their graduates with rigorous training in science, counseling, and clinical skills. The training criteria are set by a national accreditation body. Following graduation from a accredited institution, certification is achieved through successful completion of a national certification exam. State licensure is the last step in this process to ensure that providers of genetic counseling services have appropriate training and credentials to keep the citizens of Wisconsin safe. Currently, there is no legal specification in Wisconsin for who may use the title of genetic counselor or practice genetic counseling. Licensure for genetic counselors is an important mechanism by which consumers of genetic counseling services can identify appropriately qualified providers.

Please consider moving this bill forward for genetic counselor licensure.

Sincerely yours,

Catherine A. Reiser

Catherine A. Reiser MS CGC
Professor (CHS), Department of Pediatrics
University of Wisconsin-School of Medicine and Public Health
Distinguished, Clinical Genetic Counselor
Director, Genetic Counselor Training Program University of Wisconsin-Madison Room
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versiti™

December 6, 2019

Representative David Steffen
Wisconsin State Capitol – Room 21 North
P.O. Box 8953
Madison, WI 53708

Dear Representative Steffen:

Versiti, Inc., a national leader in blood health innovation, supports efforts that will improve access to quality healthcare services, including genetic counseling services, in Wisconsin. We support the Wisconsin Genetic Counselors Association's efforts to secure licensure for genetic counselors in Wisconsin as a means towards this end.

The field of medical genetics has experienced tremendous growth in recent years that has impacted virtually all areas of medicine. Correspondingly, the importance of providing quality genetic counseling services is even more important since consumers are increasingly making healthcare decisions based upon genetic risk factors and results of a variety of genetic tests. The growing complexity of genetic tests and emergence of direct-to-consumer genetic tests further highlights the need for ensuring access to quality genetic counselors.

Genetic counselors are Master's trained health care professionals who provide consumers with information, education, counseling, advocacy and emotional support for medical conditions that are either entirely or partially determined by genetic factors. Licensure for genetic counselors is critical to ensure that providers of genetic counseling services have appropriate training and credentials so that individuals receive proper information and care. Currently, there is no legal specification in Wisconsin for who may use the title of genetic counselor. Licensure for genetic counselors is an important mechanism by which consumers of genetic counseling services can identify appropriately qualified providers.

Please consider championing legislation for genetic counselor licensure.

Sincerely yours,

Chris Miskel

Chris Miskel
President and CEO
Versiti

638 N 18th Street / PO Box 2178 / Milwaukee, WI 53201-2178 / **versiti.org**

Examples of Harm from MCW

A young man in Wisconsin who was legally blind was convinced he had a dominant condition based on previous medical provider feedback and some of his own research. He wasn't going to have children because he wouldn't "wish this on anyone", as he believed he was at a 50% chance for passing the condition on to children. He was seen by a genetic counselor as he wanted testing for his own future treatment. The genetic counselor was able to counsel him that his family and personal history really supported a recessive condition. His testing came back confirming the suspicion of a recessive retinal dystrophy, meaning there was a low risk he would have a child affected with this condition. He and his partner were excited (he was yelling to her over the phone and then had her join the call) were excited to learn this information, and after testing the partner, they very likely will be able to have their own children without fear.

A patient in Wisconsin was not offered a standardly recommended first trimester ultrasound by her OB/GYN. Because of this, she did not find out that her unborn baby was missing a brain and skull until halfway through her pregnancy.

A patient in Wisconsin requested chromosome screening for her pregnancy and her obstetrician's office facilitated the testing themselves without referring to genetics. The obstetrician's office facilitated testing for cystic fibrosis instead of cfDNA (chromosome screening) and told the patient that the baby tested negative for Down syndrome and other conditions. The baby ended up being affected with Down syndrome and therefore her pregnancy management was altered given the high risk pregnancy. The patient was blind sighted given the testing error and had less time to prepare for her baby's diagnosis.

A primary care physician facilitated BRCA genetic testing for their patient in Wisconsin. The doctor told the patient 'that she only tested positive for one variant, indicating she was not at increased risk'. This patient was counseled incorrectly. After being seen by a genetic counselor, the patient was properly informed that in fact was at an increased risk of developing cancer and should have been counseled on the changes to her medical management and her available preventative surgery options.

A in Wisconsin man was told by his primary care physician that his BRCA1 test was negative after his physician ordered the incorrect test. The patient later saw a genetic counselor and was re-testing with the correct test, identifying he was positive for the familial pathogenic variant in BRCA1. He has now taken steps for early cancer detection by being screened for breast cancer and prostate cancer.

Patient in Wisconsin was referred to genetics by her primary obstetrician at the end of her pregnancy because patient again expressed concern about her family history of Hemophilia after previously being told by OB that she had a low risk of having an affected child. After being seen by a genetic counselor, genetic counselor determined that patient has 100% chance of being a carrier and there is a 50% chance

that her male fetus will be affected with Hemophilia. Because boys with Hemophilia are at risk for complications at delivery, genetic counselor was able to coordinate plan of care for infant at birth to prevent potential complications. The patient had very little time to prepare for the change in her birth plan due to the misinformation she had originally been given and the delay in a timely referral to genetics.

Patient in Wisconsin with pregnancy affected by multiple ultrasound anomalies was counselled by referring maternal fetal medicine specialist to only have a screening test performed and follow-up with diagnostic testing if the screening test is abnormal. After normal screening tests, patient met with a genetic counselor and was counseled regarding benefit of diagnostic testing. She underwent procedure and pregnancy was found to be affected with a genetic condition. After further testing, it was determined that the patient also has this condition. This led to further preventative screening for the patient and her living children.

GUNDERSEN
HEALTH SYSTEM®

May 26, 2021

Senator Mary Felzkowski, Chair
Room 415 South
State Capitol
PO Box 7882
Madison WI 53708

Senator Rob Stafsholt, Vice-Chair
Room 15 South
State Capitol
PO Box 7882
Madison, WI 53708

Re: Support for Senate Bill 259

Dear Chair Felzkowski, Vice-Chair Stafsholt, and members of the Senate Committee on Insurance, Licensing, and Forestry:

My name is Becky Pabst and I am the Lead Genetic Counselor at Gundersen Health System and a representative on the Wisconsin Cancer Council. I am here today representing both Gundersen Health System and the Wisconsin Genetic Counselors Association. I appreciate the opportunity to provide testimony on Senate Bill 259 in support of licensure of genetic counselors in Wisconsin.

Genetic Counseling licensure will protect the public. Licensure will ensure individuals and families can identify qualified genetic counselors in the State of Wisconsin and ensure our neighbors receive quality genetic counseling services.

The exploration of the genetic code is rapidly expanding, and this brings many more questions than answers regarding the meaning and utility of this information. Genetic Counselors that are trained and qualified to help navigate these complexities are not easily identifiable in States without licensure. With the demand going up, someone less qualified is going to step into this role and the risk for harm is real.

For instance, in 2019, a holistic wellness practitioner in Wisconsin advertised themselves as a genetic testing advisor, able to provide genetic cancer risk assessment and genetic testing with follow-up genetic counseling. This person joined the Wisconsin Cancer Council, portraying themselves as a genetic counselor and solicited business. While this person may have built up their skill set, offering advice with good intent, they still misrepresented themselves as a qualified

Gundersen Lutheran Medical Center, Inc. | Gundersen Clinic, Ltd.
External Affairs Department 1900 South Ave., Mailstop: SIMS-000, La Crosse, WI 54601
Email: ExternalAffairs@gundersenhealth.org Phone: (608) 775-1400

and educated Genetic Counselor. Don't patients and their families deserve to know who has these qualifications? And don't patients and families have the right to make a choice about where they get their care based on that information?

Unqualified providers may request unnecessary or incorrect tests, misinterpret results of genetic testing or under or overestimate the risk of genetic disorders—potentially putting patients at risk. Passing this bill will ensure minimum standards for academic background, clinical experience, and skills necessary to use the title Genetic Counselor. Without licensure the patients and the State will have no recourse when bad things happen.

Genetic Counselors provide current and accurate information about genetic testing options for hereditary health conditions. For those families with a preexisting hereditary condition, we are uniquely educated and trained to provide health information in a way families can understand. We are also ideally aligned in the healthcare system to provide support and advocacy for the patient and their family, as well as assist them with care coordination of screening or management options. Genetic counselors allow for more efficient and cost saving care.

Gundersen currently employs four genetic counselors in multiple departments including Oncology, Pediatrics and Obstetrics. Each year, we support approximately 2,000 families as they navigate the complexities of genetic testing and diagnosis. Our system includes a primary hospital in La Crosse, six critical access hospitals and over 70 clinics throughout the Upper Midwest. We are committed to supporting public policy to enrich every life through improved community health, outstanding experience of care, and decreased cost burden.

Gundersen believes licensure for genetic counselors is important to ensure Genetic Counselors have appropriate training and credentials as genetic testing opportunities expand. We are pleased by the definition of who is qualified as a genetic counselor included in Senate Bill 259; this reassures community members and patients they are being assisted by qualified and certified genetic counselors who have undergone specialized education and training to provide care.

On behalf of Gundersen Health System and the Wisconsin Genetic Counselors Association, we are pleased to support Senate Bill 259. We look forward to advancing genetic counselor services within the healthcare community and will continue to support efforts made to further ensure care is available close to home.

Thank you for taking time to hear my testimony; I am happy to answer any questions.

Becky Pabst, MS, CGC
Lead Genetic Counselor
Genetic Services
Gundersen Health System

National Society of Genetic Counselors

LICENSURE FOR WISCONSIN GENETIC COUNSELORS

Approximately 100 genetic counselors currently live or work in Wisconsin. More than 60% of Wisconsin genetic counselors work full- or part-time in a clinical setting and provide genetic counseling services to patients.

Who Are Genetic Counselors?

- Genetic counselors are healthcare professionals who have a specialized graduate degree, academic training, and experience in both medical genetics and counseling.

What Medical Services do Genetic Counselors Provide?

- Genetic counselors work with physicians, as part of a multidisciplinary team, or independently, to provide genetics services to families and/or individuals.
- Genetic counselors consult with patients and families in reproductive genetics, pediatric genetics, cancer genetics, cardiovascular genetics, neurogenetics, and other genetics settings.
- Genetic counselors provide genetic counseling for patients and families at increased risk for a variety of genetic conditions with onset at birth through adulthood.
- Genetic counselors evaluate and assess risk for a genetic condition, educate patients about the condition and available management options, facilitate genetic testing and test interpretation when available and appropriate, and assess and address the psychosocial impact of a genetic condition in order to help families adapt.

Why Do Genetic Counselors Need to be Licensed?

- Wisconsin currently has no legal standard to determine who can represent themselves as genetic counselors.
- Licensure would protect the citizens of Wisconsin by ensuring that genetic counselors practicing in Wisconsin:
    - Have appropriate training in medical genetics and genetic counseling
    - Are certified by the American Board of Genetic Counseling or the American Board of Medical Genetics
    - Collect a minimum number of continuing education units to stay up to date in the rapidly changing field of genetics.
- Licensure would also create a means for Wisconsin to regulate genetic counseling services.
    - Wisconsin would define what genetic counselors can do

- Wisconsin would prevent unqualified individuals from practicing genetic counseling within the state
- Wisconsin could suspend or revoke licenses of genetic counselors who cause harm to citizens of Wisconsin through inadequate genetic counseling.

- Licensure will positively impact the Wisconsin economy:
  - Genetic counselors ensure appropriate tests are ordered and interpreted to facilitate proper medical management while reducing healthcare costs
  - Licensure would help attract trained genetic counselors to Wisconsin
  - Licensure would be budget-neutral for Wisconsin, as the cost of regulation will be offset by the fees collected for obtaining a license.

- Genetic Counselors adhere to ethical practice and evidence-based competencies, quick link references below
  - NSGC Scope of Practice
  - https://www.abgc.net/for-diplomates/practice-standards/
  - https://www.nsgc.org/p/cm/ld/fid=12
  - https://www.aruplab.com/files/resources/news/GeneticCounselorReview.pdf

National Society of Genetic Counselors

Genetic Counselors Bring Quality and Cost-Effective Care to Patients

Genetic counselors are healthcare providers with significant training and expertise in genetics. Although providers without specific genetics training use genetics in their practices, surveys show that only 25 percent of non-genetics physicians rate themselves as having good-to-excellent knowledge of genetics, while 72 percent have a fair-to-poor knowledge. Genetic counselors serve as effective genetic service care coordinators for patients treated by non-genetics physicians, ensuring the delivery of high quality genetics services.

Genetic counselors provide care that demonstrates both increased quality and cost-effectiveness. This paper will demonstrate that:

(1) Genetic counselors are better able to identify family members at risk for disease and death as compared to non-genetics providers;
(2) Genetic counselors order (or collaborate with an ordering physician) appropriate genetic testing in a manner that often reduces overall costs as compared to non-genetics providers;
(3) Genetic counselors' clinical activities enable cost-effective care.

Background: Genetic Services in Patients and Family Members

Genetic services as part of medical evaluation offer several benefits to patients. First, finding a mutation can confirm a diagnosis when clinical diagnoses are not made with certainty. Second, treatment and prevention is tailored to the risks conferred by specific genes and mutations. Finally, identifying the genetic mutation in a family enables relatives to undergo genetic testing to learn if they carry the same disease-causing mutation.

For many genetic conditions, 50 percent of first-degree relatives (siblings, parents, children) of a person with a genetic mutation will also carry a mutation and are at risk to manifest the disease. Identifying those who carry a mutation offers the opportunity for preventive screening and treatment, thus lowering the chance of disease manifestations. Moreover, identifying those family members who do *not* carry a mutation eliminates the need for expensive clinical follow-up.

Genetic counselors communicate risk information regarding genetic conditions to individuals and their family members before and after genetic testing. This information is based on a thorough assessment of the family medical history and interpretation of genetic test results. Patients and their physicians use this genetic information to make informed medical decisions. Health care providers with a limited knowledge of key cancer genetics concepts may inadequately collect family history, inaccurately assess risk, and incorrectly interpret diagnostic evaluations.[1] If errors due to a lack of

knowledge are made, they can lead to detrimental decisions, depriving patients of valuable information and medical options. For example, patients may undergo unnecessary preventive surgery (such as mastectomy) if an unskilled provider misinterprets the results of DNA tests for genetic susceptibility to breast cancer. Misinterpreting test results could falsely reassure patients, leading them to forego recommended cancer screening. Lack of appropriate screening could lead to the unfortunate development of advanced stage, incurable cancer.

The following case examples demonstrate genetic counselors' value with respect to quality of care and cost.

Genetic counselors are more effective at identifying individuals at risk for sudden death than non-genetics providers.
Case example: Inherited Cardiac Disease

Inherited cardiac disease, particularly cardiac channelopathies and cardiomyopathies, claims approximately 27,000 lives each year. Since some disease types have few warning signs and are as common as 1 in 500, knowing that one is at risk and implementing appropriate preventive measures is vital. After a patient is identified with an inherited cardiac disease, family members should also consider genetic testing.

PGxHealth, a division of Clinical Data Inc., has been a leader in genetic testing for potentially lethal heart conditions since 2004. Recently, PGxHealth reviewed historical patterns of tests ordered by two groups of physicians: those who work with a genetic counselor and those who do not. Analysis of testing patterns over a two-year period revealed that providers who work with genetic counselors ordered twice as many family tests than providers who do not collaborate with genetic counselors. Specifically, for each family undergoing genetic testing, genetic counselors ordered 1.02 family tests compared to physicians who did not collaborate with a genetic counselor and ordered 0.54 family tests.

This data shows that family members of a patient who suffers from hereditary heart disease may not be aware of the threat posed to them if the patient did not see a genetic counselor. The actor John Ritter and the Boston Celtic Reggie Lewis both died unexpectedly from inherited cardiac conditions. Awareness of the heritability of the disease may have increased surveillance of these individuals, or possible treatments that would have prolonged their lives. John Ritter's brother has since undergone surgery to help correct his cardiomyopathy and is a proponent of genetic counseling for family members.

Genetic counselors have the expertise to offer targeted, less expensive genetic testing.
Case example: Multiple Endocrine Neoplasia

Multiple Enodcrine Neoplasia Type II (MEN) is a hereditary cancer syndrome that is lethal if not detected at a young age. Mayo Medical Center in Rochester, MN recently analyzed the genetic services for MEN.

Genetic testing for the first person in a family often involves full sequencing of many genes, a process similar to proofreading several long sentences. Once a misspelling, or mutation, is identified, family members can be tested – in a less expensive manner – for that one site-specific genetic change rather than through full sequencing.

Mayo Laboratory examined the MEN tests ordered for family members, which should have been the less expensive, site-specific testing. Almost half of the family-specific tests run by the laboratory were incorrectly ordered, mostly by non-genetic counselors. Out of 50 consecutive MEN site-specific family tests run, 22/50 (44 percent) were originally ordered as full-gene sequencing even though the less expensive test was more appropriate. Of those 22 incorrectly-ordered tests, 95 percent were made by providers who did not consult a genetic counselor. Full sequencing of the MEN gene costs $630, while a site-specific test costs only $400. Genetic counselor involvement in this one small cohort saved 22 x $230 = $5060. Incorrectly testing family members for the full-testing panel when the less-expensive testing is more appropriate wastes resources and stems from the lack of familiarity with genetic testing.

Although MEN is a rare disease, this pattern is present with many common disease types. Furthermore, even though the price differential between full-sequencing and site-specific testing is only $230 per patient for MEN; the price differential for other diseases can be as large as $4500. This demonstrates large cost-savings by referring to the expertise of genetic counselors in the routine care of patients in need of genetic testing.

Proper Genetic testing can keep laboratory costs as low as possible. Genetic counselors working in the clinic are in an optimal position to administer testing in the most appropriate and cost-effective manner.

Genetic testing and subsequent follow-up is cost-effective.
Case examples: Long QT Syndrome and Breast Cancer

In assessing the downstream effects of genetic testing, numerous studies show that appropriate genetic testing and subsequent follow-up are cost-effective. Two examples include Hypertrophic Cardiomyopathy and Breast Cancer.

Hypertrophic cardiomyopathy (HCM) affects 1 in 500 people and can cause sudden and unexpected cardiac death. Costs associated with the disease are driven by medication, surgery, an implantable defibrillator to restart the heart should it stop beating, and regular clinical screening. This clinical screening, performed for patients with the disease and those at risk, is generally performed every three to five years and can include an exercise stress test, electrocardiogram (EKG), echocardiogram and MRI. It can easily cost $1,000 or more for each assessment. The 50 percent of asymptomatic family members who do not carry a genetic mutation can forego all the expensive annual screening. Thus, identifying those who are not at risk for HCM and can dispense with screening, which is a significant source of cost savings.

Breast cancer screenings follow a similar pattern. Of the almost 200,000 American women diagnosed with breast cancer in 2009, 5-10 percent have an inherited form of the disease caused by a mutation in a breast cancer gene.[2] If a woman and her relatives know they carry this mutation, they can opt for preventive surgery to remove the breasts and ovaries. This preventive measure costs $15,925 while treatment for breast or ovarian cancer costs $26,412 and $55,323 respectively for the first year alone.[3] Undergoing these preventive surgeries and avoiding the costs related to a cancer diagnosis is certainly cost-effective.

Genetic counselors are better able to prescribe appropriate genetic testing for patients and their families and can help drive cost-effectiveness with respect to genetic disease.