MICROFILM DIVIDER

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SFN 2053 (2/85) 5M

ROLL NUMBER

DESCRIPTION

2166

2005 SENATE HUMAN SERVICES

SB 2166

2005 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2166

Senate Human Services Committee

☐ Conference Committee

Hearing Date January 19, 2005

Tape Number	Side A	Side B	Meter #
1	x		4,930-6100
1		x	1-4684
2	x		5050-6189
2		x	850-1350
Committee Clerk Signature			

Minutes:

Chairman Lee opened the hearing on SB 2166 and turned the hearing over to Vice Chairman Dever.

All members were present.

Testimony in favor of SB 2166

Senator Judy Lee is a sponsor of this bill and introduced it. The bill relates to treatment and care for pain. See written testimony (Attachment 1)

Bruce Levi, North Dakota Medical Association

See written testimony (Attachment 2, 2A, 2B). Mr. Levi mentioned that Dr. Nick Newman was present if there were any questions on chronic pain.

Sen. Dever: What happens when someone has a condition with pain and becomes addicted?

Dr. Newman: The original language in the statute was appropriate at the time it was first enacted, but now it is outdated and should be changed. Bruce has already listed the problems with the language. The use of intractable pain is a problem. It predisposes that there isn't a treatable cause for the pain, and that's not often the case. Current terminology implies that opiates for pain management is not a regular part of professional practice, and, in fact, it is very much so. World Health Organization has defined and suggest the use therapies for pain on a graded level, with pain from 1 to 10, with mild pain from 1-3 be treated with Tylenol, etc.; but when pain is 3 or above, opiates are recommended and routinely used for pain management, and it shouldn't be considered a last resort, as the current law suggests.

Dr. Newman gave other examples of where the language in the bill is obsolete. He said the proposed changes address the language problem. There is a problem with undertreatment for pain because physicians feel someone is looking over their shoulder.

Dr. Newman answered Sen. Dever's earlier question regarding addiction resulting from being prescribed pain medicine. Dr. Newman explained that when the use of opiates are used for post-operate patients and many times with chronic pain a pump is used. However, even with these self-administered drugs, the side effects are minimal. Sometimes a person will develop a tolerance, but addiction is much overplayed. Dr. Newman explained the difference between physical addiction, mental addiction and pharmacological tolerance.

Sen. Warner asked about end of life issues and ethical decisions that need to be made. Dr. Newman answered that a physician is morally obligated to ease someone's pain, which is an accepted ethical medical practice

Christopher Dodson, Executive Director of the North Dakota Catholic Conference

Mr. Dodson testified that we've come a long way in managing pain in the last 10 years and explained why we were under treating pain. Churches have come a long way too. A Christian belief was that suffering equaled pain, when in reality suffering is a spiritual struggle, and people have a right to treat their pain. He still runs into physicians that think, for religious reasons, that people should suffer in pain, and that's not an orthodox Christian teaching. It's been our position that pain should be managed. This bill gives a better comfort level, that providers will adequately take care of people's pain.

Chairman Lee: One of the things I've read is the under treatment of children's pain.

Roger Wetzel:

Mr. Wetzel distributed a booklet titled It's OK to talk about dying." See attachment 3. He discussed the need for treating the dying patient's pain needs.

Neutral testimony

Rolf Sletten, Executive Secretary, North Dakota Board of Medical Examiners

See written testimony (Attachment 4)

Chairman Lee disagreed with his interpretation of section 5 and did not like the changes proposed by the medical examiner's office. It was agreed that Dr. Sletten and Dr. Levi would meet to come up with language that adequately satisfied both parties. (Attachment 5)

Chairman Lee closed the public hearing on SB 2166.

Chairman Lee said Dr. Nammour will provide the committee with a rebuttal to the testimony in opposition to the bill.

Sen. Dever said he talked with Sparb Collins and asked why his numbers were different on the amendment he had. Sparb said they're different because the fiscal note includes different categories.

Discussion ended.

Chairman Lee reopened the discussion on this bill.

There was general discussion among the committee members on the use of pain medication and addiction. They want to wait for Bruce Levi and Rolf Sletten to come in with something better. Sen. Brown mentioned that Rolf is looking at the bill from the policy standpoint. Chairman Lee supports the bill as written. If a patient comes in with an addiction meth, heroin, etc., they should still be able to get pain relief.

Sen. Lyson still wasn't sure but thought Rolf was too narrow in his thoughts.

Discussion on this ended.

2005 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2166

Senate Human Services Committee

❑ Conference Committee

Hearing Date January 25, 2005

Tape Number	Side A	Side B	Meter #
3	x		1565-2970
Committee Clerk Signature			

Minutes:

Chairman Lee reopened discussion on SB 2166.

A conference call was placed to Dr. Preston Stein.

Chairman Lee introduced the committee and Bruce Levi and asked Dr. Stein if he had any comments on pain management and the reason the committee should consider this amendment.

Dr. Stein: The changes that are proposed would take away the fear doctor's have with prescribing the necessary drugs for people in pain, especially those with chemical dependencies. The people with chemical dependencies shouldn't be treated as second class citizens and be forced to suffer needlessly.

Chairman Lee: Have there been instances in other states where doctors have been censored by their board of medical examiners for prescribing pain killers in certain situations, particularly for patients in hospices, where that was a major portion of their practice--being disciplined.

Dr. Stein: Repeated cases have been brought up-and one of the big hesitancies of physicians, if they work in a hospice situation or not, they recognize the need for proper pain control and been punished for taken the patients need first. We need to remove the barriers so patients can receive the pain medication they need.

Dr. Stein stated that he had seen the bill and the amendment and was very happy with the wording and the change, the old wording was archaic.

Chairman Lee thanked Dr. Stein for his opinion, Bruce Levi and Rolf Sletten for their input.

Sen. Warner asked a question about pain and withdrawal caused by addiction. Bruce Levi answered (tape 3 side A meter 2190-2165)

Senator Warner moved do pass on the Sletten-Levi amendmenton SB 2166, seconded by Senator Dever.

Vote: 5 yeas, 0 nays, 0 absent

Senator Brown moved do pass on amended bill, seconded by Senator Dever. Vote: 5 yeas, 0 nays, 0 absent. Carrier: Senator Richard Brown

Date: 1-25-05
Roll Call Vote #: 1

2005 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2166

Senate **Human Services** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Pass amendment

Motion Made By Sen Warner Seconded By Sen Dever

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee - Chairman	✓		Sen. John Warner	✓	
Sen. Dick Dever - Vice Chairman	✓				
Sen. Richard Brown	✓				
Sen. Stanley Lyson	✓				

Total (Yes) 6 No Ø

Absent Ø

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Date: 1-25-05
Roll Call Vote #: 2

2005 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2164

Senate **Human Services** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Pass

Motion Made By Sen Brown Seconded By Sen. Dever

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee - Chairman	✓		Sen. John Warner	✓	
Sen. Dick Dever - Vice Chairman	✓				
Sen. Richard Brown	✓				
Sen. Stanley Lyson	✓				

Total (Yes) 5 No 0

Absent 0

Floor Assignment Sen. Brown

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2166: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (5 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2166 was placed on the Sixth order on the calendar.

Page 1, line 7, overstrike "a pain state"

Page 1, line 10, after "~~efforts~~" insert "acute pain and chronic pain. Acute pain is the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus and typically is associated with invasive procedures, trauma, or disease, and is generally time-limited. Chronic pain is a state"

Page 2, line 15, after "substances" insert "not related to treatment for pain"

Page 2, line 16, overstrike "controlled substances" and remove "for pain"

Page 2, line 17, overstrike "to a person the physician knows is using", remove "those", and overstrike "controlled substances for nontherapeutic" and insert immediately thereafter "any drug legally classified as a controlled substance or as an addictive or dangerous drug for other than medically accepted therapeutic"

Renumber accordingly

2005 HOUSE HUMAN SERVICES

SB 2166

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. **SB 2166**

House Human Services Committee

❑ Conference Committee

Hearing Date **February 28, 2005**

Tape Number	Side A	Side B	Meter #
1	**X**		**2,160**
Committee Clerk Signature	Janice Stein		

Minutes:

REP. CLARA SUE PRICE, CHAIRMAN Called the committee meeting to order.

SEN. JUDY LEE, DIST. 13, WEST FARGO, Introduced the bill. Stated she has been involved in a joint effort since 1998, with about fifty different entities, led by the North Dakota Medical Association, regarding matters in life and death. This was spearheaded by the former intern dean of UND of student medicine. He was the primary investigator. It involved a variety of activities and worked designs to improve care for the dying in North Dakota, and that is just the elderly. It was a wonderful experience. There were so many different groups that were involved, not only medical providers but attorneys, financial planners and clergy. One element to that project included a significant effort to expand educational opportunities on end of life care. That is one of the areas that hospice excell, is that they are very good in managing pain, which is a very important component in end of life care.

There have been doctors that have been sanctioned in some states, for prescribing pain killers and some of these physicians were medical directors of hospices. It is important that the physicians not be threatened with sanctions, if they are appropriately dispensing these medications.

Educating professionals is only one avenue that can help address the need for adequate pain management. State policies can also help to enhance or impede, pain management. In 1995, North Dakota adopted what is called the intractable pain ax, designed to encourage the appropriate treatment of intractable pain, by use of controlled substances. The legislation was sponsored by Sen. Jack Traynor, and unanimously passed in the Senate, and passed the House by a vote of 94 to 1. It gives the physicians the ability to prescribe or administer controlled substances to a patient with intractable pain, without being disciplined by the North Dakota Board of Medical examiners, or by a hospital or health care facility.

We hear a lot now about Octicontin, and the abuse that takes place. This is something that is being watched very closely.

Several months ago, I received information about laws that many of the states have adopted, including criticism of our current law, as using an outdated definition of pain, and overly restricting physicians in how they treat their patients who have a history of substance abuse or other addictive disorders. I provided that information to the North Dakota Medical Association, which after discussing the issue, came forth with a proposal for revising our current statute.

SB 2166 is the substance of that proposal.

BRUCE LEVI, REPRESENTING THE NORTH DAKOTA MEDICAL ASSOCIATION

Testified in support of the bill. Stated he also had Dr. Nick Neuman, from UND medical school

with him. See attached written testimony together with North Dakota policies evaluated, statutes and regulations.

CHRISTOPHER DODSON, EXECUTIVE DIRECTOR OF THE NORTH DAKOTA CATHOLIC CONFERENCE Testified in support of the bill. See attached written testimony.

With no further testimony, the hearing was closed.

CHAIRMAN PRICE opened discussion on SB 2166.

REP UGLEM: I move a Do Pass.

REP. POTTER: Second

CHAIRMAN PRICE: Any further discussion?

VOTE 10-0-2 CARRIER: REP. UGLEM

Date: 2/28/05 Roll Call Vote #: 1

2005 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. SB2166

House **Human Services** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass

Motion Made By Rep Uglem Seconded By Rep Potter

Representatives	Yes	No	Representatives	Yes	No
Chairman C.S.**Price**	✓		Rep.L. **Kaldor**	AB	
V Chrm.G. **Kreidt**	✓		Rep.L. **Potter**	✓	
Rep. V. **Pietsch**	✓		Rep.S. **Sandvig**	AB	
Rep.J.O. **Nelson**	✓				
Rep.W.R. **Devlin**	✓				
Rep.T. **Porter**	✓				
Rep.G. **Uglem**	✓				
Rep C. **Damschen**	✓				
Rep.R. **Weisz**	✓				

Total ( ) 10 **No** 0

Absent 2

Floor Assignment Rep Uglem

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2166, as engrossed: Human Services Committee (Rep. Price, Chairman) recommends **DO PASS** (10 YEAS, 0 NAYS, 2 ABSENT AND NOT VOTING). Engrossed SB 2166 was placed on the Fourteenth order on the calendar.

2005 TESTIMONY

SB 2166

Attachment 1

Senator Judy Lee
January 19, 2005

Senate Bill 2166

In 1998 up to the last legislative session, I participated in a joint effort of over fifty state organizations and groups led by the North Dakota Medical Association called the "Matters of Life & Death" project. It was spearheaded by the former interim Dean of the UND School of Medicine, Dr. Clayton Jensen, and involved a variety of activities and work designed to improve care for the dying in North Dakota. One element of that project included a very significant effort to expand education opportunities for professionals in North Dakota on end-of-life care, which included physicians, nurses, social workers and other professions. The education provided included a variety of topics, including the basics of good pain management.

Pain is prevalent in cancer, especially near the end of life, and in other disease and conditions. When pain is relieved there is improved quality of health and life. But, unfortunately, inadequate management of pain occurs all too often for a variety of reasons, including physician fear of regulatory sanctions. Educating professionals is only one avenue that can help address the need for adequate pain management. State policies can also help to enhance, or impede, pain management.

In 1995, North Dakota adopted what is called the "Intractable Pain Act" designed to encourage the appropriate treatment of persons with intractable pain by the use of controlled substances. The legislation was sponsored by Senator Jack Traynor and passed unanimously in the Senate and by a vote of 94-1 in the House. The law is straight forward – it gives physicians the ability to prescribe or administer controlled substances such as opioids to a patient in the course of the physician's treatment of a patient for intractable pain, without fear of discipline by the ND Board of Medical Examiners or by a hospital or other health care facility.

Several months ago I received information about laws that many of the states have adopted, including criticism of our current law as using an outdated definition of "pain" and overly restricting physicians in how they treat their patients who have a history of substance abuse or other addictive disorder. I provided that information to the North Dakota Medical Association, which after discussing the issue came forth with a proposal for revising our current statute. Senate Bill 2166 is the substance of that proposal, and I urge you to consider carefully the need to keep up with the changing environment – both in the medical advances in pain management, as well as our state policies on pain management.

Association of American Physicians & Surgeons
The Voice for Private Physicians Since 1943
1601 N. Tucson Blvd. Suite 9
Tucson AZ 85716
www.aapsonline.org

Patient Access to Pain Management:

US drug policy forces pain patients to extreme measures, turns doctors into criminals

Department of Justice interfering with state jurisdiction

Proposed remedies by state legislatures:

1. **Model legislation "Chronic Pain Treatment Act"**
2. **State licensing protections**
3. **Reporting, law enforcement education & case review (See *"Project: Communicate & Cooperate")***

Background:

The more than 48 million people who suffer chronic pain in the United States are having difficulty finding doctors to treat them as a result of misguided drug policy, law enforcement, and overzealous prosecutions – particularly by the federal government.

The 'war on drugs' has turned into a war on doctors and the legal drugs they prescribe and the suffering patients who need the drugs to attempt anything approaching a normal life.

Some states, such as Virginia, have laws that specifically state that prescribing high doses is not a violation, and 15 states have now passed some type of chronic pain act. But there are still many loopholes that allow federal prosecutors to usurp state jurisdiction.

In Sept., 2003, the DOJ arrested William Hurwitz, MD, of McLean, Virginia, who has now been indicted, imprisoned, and had all assets seized for prescribing legal pain relief that had been approved and supervised by the Virginia Board of Medicine.

The result of prosecutions such as those against Dr. Hurwitz and more than 30 others tracked by AAPS is that doctors are afraid to prescribe opioids, and patients can't get the drugs they so desperately need. Physicians are being threatened, impoverished, delicensed, and imprisoned for prescribing in good faith with the intention of relieving pain. And their patients have become the collateral damage in this trumped-up war.

Some patients require very large doses, sometimes literally hundreds of pills in each prescription – a number that may seem alarming to people unfamiliar with current treatment standards in pain management. Other patients report that they have lied about being heroin addicts in order to get pain medication at methadone clinics.

The situation has become so critical that AAPS has issued a serious warning to doctors:

> "If you're thinking about getting into pain management using opioids as appropriate -- DON'T. Forget what you learned in medical school -- drug agents now set medical standards. Or if you do, first discuss the risks with your family." (See www.aapsonline.org)

If this continues, pain patients will be back in the Dark Ages of 'pain clinics' that basically told the patients they had to learn to 'live with the pain' – except possibly if they had cancer and then they wouldn't have to live with it for very long -- and there won't be one doctor left willing to prescribe the drugs that patients so desperately need," said

Attachment 2

ND Medical Association

Testimony in Support of Senate Bill No. 2166 -- Pain Management
Senate Human Services Committee
January 19, 2005

Senator Lee, Members of the Senate Judiciary Committee, I'm Bruce Levi representing the North Dakota Medical Association. The Association is the professional membership organization for physicians, residents and medical students in North Dakota, with 1,075 members.

The North Dakota Medical Association supports Senate Bill No. 2166, and the intent of the measure to strengthen state policy encouraging adequate treatment for pain.

It is well documented that unrelieved pain continues to be a serious public health problem for the general population in the United States. This issue is particularly relevant for children, the elderly, minorities, patients with active addiction or a history of substance abuse, developmental disabilities, as well as for those with serious diseases such as cancer, HIV/AIDS, or sickle cell disease. Clinical experience has demonstrated that adequate pain management leads to enhanced functioning and increased quality of life, while uncontrolled pain contributes to disability and despair. There are many safe and effective drug and non-drug ways to manage pain, which vary according to the individual needs of the patient. However, there is a general medical and regulatory consensus that opioid analgesics are necessary to maintain public health; they often are the mainstay of treatment, particularly if pain is severe.

Many states, beginning with Texas in 1989, adopted legislation called "Intractable Pain Treatment Acts" or "IPTAs" in an effort to address inadequate pain management. North Dakota adopted its IPTA in 1995. The legislation was sponsored by Senator Jack Traynor and passed unanimously in the Senate and by a vote of 94-1 in the House. The main goal of these laws is to address physician reluctance to prescribe opioids for the treatment of chronic pain, due to their concern about regulatory scrutiny, by providing protection from discipline by state medical boards. State medical boards have taken additional steps in many parts of the country to improve pain management, including clarification of policy to address physician reluctance to prescribe.

In fact, original guidelines adopted by the Federation of State Medical Boards in 1998 were adopted in whole or in part by 24 state medical boards. These guidelines told physicians they need to view pain management as important and integral to the practice of medicine.

The Federation of State Medical Boards adopted a new policy in May 2004 -- *Model Policy for the Use of Controlled Substances for the Treatment of Pain* – and a copy of that new policy is included in your handouts. That policy communicates the following message to physicians, if adopted by the state medical board:

> *That the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physician have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes.*

SB 2166 would update North Dakota's "Intractable Pain Treatment Act," Chapter 19-03.3 of the North Dakota Century Code. Section 1 of the bill would incorporate a definition of "chronic pain" used by the Federation of State Medical Boards in the *Model Policy for the Use of Controlled Substances for the Treatment of Pain.* Other language in the current law would be amended to use the term "pain" rather than "intractable pain," consistent with the new definition. In addition, section 5 of the bill would narrow current language that restricts medical decisions in cases involving a patient who a physician knows is using controlled substances for nontherapeutic purposes. That language is proposed to be narrowed to better reflect current pain management practices that recognize that patients with active addictive disorder or a substance abuse history are at increased risk of receiving inadequate pain management.

Section 1: The Federation of State Medical Boards' Definition of "Pain"

Section 1 of the bill would change the definition of "intractable pain." The current definition defines "intractable pain" as a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure

of the cause of the pain is possible or none has been found after reasonable efforts." This definition of pain was reviewed by the Pain & Policy Studies Group of the University of Wisconsin's Comprehensive Cancer Center in 2000 and 2003. The Group noted that the state's definition of "intractable pain" may impede pain management by implying that opioids are not a part of professional practice and that opioids are a last resort. Handouts are provided with specific information on the Pain and Policy Group's review of North Dakota's law.

It is also suggested that the current definition of "intractable pain" implies that some individuals may develop pain that cannot be treated. In addition, the Act requires that the physician "prove a negative;" that is, the physician must prove that there is not a treatable cause for the pain, or that the pain does not respond to treatment. The definition also implies that opioids are a last resort; that the law requires a physician to undertake a potentially extensive series of diagnostic and/or treatment procedures in order to qualify for protection under the statute, thereby delaying treatment.

The new proposed definition of "pain" in section 1 of the bill comes from a model policy recently approved by the Federation of State Medical Boards -- *Model Policy for the Use of Controlled Substances for the Treatment of Pain.* SB 2166 incorporates the new model policy definition of "chronic pain." The Federation states in the policy that it recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins.

Section 5: Addressing Patients with Addictive Disease

Section 5 of the bill would address the application of the protection offered under chapter 19-03.3 to persons with certain characteristics, i.e., cases involving a patient with pain who a physician knows has an active addictive disorder or a substance abuse history. The Federation of State Medical Board's new *Model Policy for Use of Controlled Substances for the Treatment of Pain* recognizes the special needs of these patients: "Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may

require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients."

Organizations that have produced statements of patients' rights with respect to pain treatment are in agreement with the Joint Commission on Accreditation of Healthcare Organizations which states that "all patients have the right to the appropriate assessment and management of pain." Policy statements from the American Society of Addiction Medicine recognize that these individuals present a number of challenges when they experience pain that can be relieved with opioids, but that they nonetheless can and should receive such treatment if it is medically appropriate. Individuals with current or past histories of substance abuse "should be viewed as having a concurrent illness that requires a degree of expertise for its management, and they should not forfeit their right to pain control because of this concurrent illness."

Texas, the first state to adopt an Intractable Pain Treatment Act in 1989, has since repealed the language restricting prescribing to patients with addictive disease.

Thank you for the opportunity to address the concerns surrounding the introduction of SB 2166.

Attachment 3

Are you afraid to start the conversation?

Advance Care Planning Resource Guide for North Dakotans

In This Guide

Dear Fellow Citizens of North Dakota,

Caring for a family member or client at the end of life can be one of the most difficult experiences any of us will face. We all want life's end to be peaceful and pain free. We also want to maintain the dignity of people who are dying, and to follow their choices and wishes. Improving care at the end of life is the goal of North Dakota's Matters of Life and Death project. It is also a national goal that is being addressed in many other states.

Funded by The Robert Wood Johnson Foundation and Dakota Medical Foundation, our Matters of Life and Death project is supported by more than 50 statewide organizations, led by the North Dakota Medical Association.

We have found that many of our state's citizens do not know where to get the information necessary to help loved ones receive the care they want and need at end of life. We also have found that many of our state's citizens are unaware of the option to complete advance directives, such as a living will or durable power of attorney for health care.

There is much that professionals can do to improve care at the end of life. But there are also many things you and your family can do. You can start important conversations about your wishes for your own end-of-life care. You can communicate these wishes to your doctor and pastor. You can make plans and complete documents to make sure your wishes are followed.

As participants in the Matters of Life and Death project, it is our hope that this guide will help you and your loved ones attain a peaceful and comfortable experience at the end of life.

Sincerely,

Rodger Wetzel
Steering Committee Chair

Bruce Levi
Project Director

Susan Fuglie
Steering Committee Vice Chair

Clayton Jensen
Project Investigator

The Most Important Conversation

ONE FAMILY'S STORY ...

For reasons unknown—maybe because her mother was a former nurse—care at the end of life was an issue Anne had talked about with her parents for a long time.

"It just came up really naturally," recalls Anne, "especially as they had friends who were aging or ill. And my parents must have visited about it between them. They were very unified about what they wanted."

After Anne's mother was hospitalized with a brain hemmorhage, Anne realized that not only had her parents "talked the talk," but that the right paperwork had been done, too. Says Anne: "We had the legal papers—the advance directives—and I knew where they were."

Anne's mother had also spoken with her physician about the kind of care she wanted at the end of life.

"Nobody has ever been clearer with me about her wishes than your mother," the doctor told Anne.

The most important conversation you hold while you're living ... may be about dying. Most of us know we *should* talk to a variety of people about our end-of-life wishes. It's just that, often, we *don't*.

Yet, if we can document and discuss in advance our end-of-life wishes, a conversation that once seemed scary can actually become comforting.

It really *is* OK to talk about dying. It *has* to be. Use this guide to help you start to ...

- Hold conversations about your end-of-life wishes with family, health care providers and others who may be involved in your care.
- Document those wishes, in writing, by preparing an advance directive.

If in the future you are unable to communicate or make decisions, your family, physician and others will know your wishes.

Who needs to talk about it?

You need to start this important conversation if you ...

- Are an elderly person, or have loved ones who are aging.
- Want to make sure your wishes for end-of-life care, at any age, are understood and followed.
- Don't want to burden family members or others with decisions or misunderstandings when you are dying.
- Want to achieve peace of mind for you and your loved ones.

Are Followed

How do you *know* that your wishes for end-of-life care will be followed? How can you be certain, for example, that you won't receive unwanted medical treatments that will sustain your life, even if your quality of life is poor? Or, how do you know your life will be prolonged, if you wish, as long as possible?

There is only one way to be as certain as you can that your family, health care providers and others will understand and follow your end-of-life wishes: *You must put them in writing,* using a special form called an "advance directive." (More information about and an example of these forms are found on pages 7 - 12 of this resource guide.)

Keep in mind that ...

- If you do not have an advance directive in place and you become seriously ill or injured, your doctors, hospital staff and loved ones will do the best they can.
- **However, without clear direction from you, your loved ones may have to guess what you would want.**
- If there is any uncertainty about your wishes, care *could* be delivered that may *not* be consistent with your wishes.
- **Remember, if you want people to know—and follow—your wishes, you should talk with them about your preferences *and* have a written and signed advance directive in place.**

Let this guide help you start the conversations to get that done.

A GIFT YOU CAN GIVE

Talking with other people about your wishes for the end of life is a true gift you give to those you love!

When you start the conversation about dying—and when you document and discuss your wishes through an advance directive—you can help family, friends, clergy and others who might otherwise be uncertain about what you would want done at the end of your life.

This vital conversation is also a great opportunity to talk about very meaningful issues:

- Your past
- Love and forgiveness
- Relationships
- Hopes and fears
- Spiritual beliefs

How to start the conversation

You need to talk with your loved ones and health care provider about your wishes, so that they understand how you want to be treated at the end of life.

Sometimes it is difficult to begin a conversation about dying. But it really *is* OK to do so. How can you start?

- Use this guide and the sample form as a starting point for writing down notes and questions you may have about your options and wishes for care at the end of life.
- Talk with those closest to you about your values and preferences for end-of-life care. This may be an ongoing discussion for a while, and that's OK, too.
- Talk to your health care provider about medical options and the kind of treatment you want or do not want for end-of-life care.
- Think of other people—including your pastor or attorney—to whom you may also want to talk about dying.
- Document your wishes by completing and signing an "advance directive" form. (More information and a sample form are found on pages 7 -12 of this guide.)

Conversation starters ...

- Encourage family members to discuss their plans by talking about your own: "Mom, did you know that I have filled out a living will?"
- Open conversation by relating to a personal event: "When I was a girl, people never talked about dying, but I think it's important."
- "(Doctor, Pastor, etc.), I would like to talk about my options for the end of life and make sure you understand what I want when that time comes."
- Tell a story about someone else's experience with an end-of-life situation and relate that to what you would like your own experience to be.

ONE FAMILY'S STORY ...

While telling family about your wishes may not make all decisions easy, it does provide a "roadmap" to guide them, Anne says.

Following a brain hemmorhage, Anne's mother underwent surgery and a variety of treatments. Gradually, though, her condition worsened. Knowing her mother expressly did *not* want to be permanently sustained by artificial means—particularly after she became unable to speak or take care of herself—Anne and her father were finally able to "let go," allowing Anne's mother to die naturally once there was no hope of recovery.

"The gift she gave us was immeasurable," says Anne. "She made it easier for us to make the decision to withdraw futile treatment. Knowing we honored her wishes has made it easier to accept what's happened."

Questions to Consider

Are you getting ready to talk about dying? This Conversation Checklist offers some questions about different aspects of dying to help you get started. Make sure your specific wishes related to these questions are indicated when you create your advance directive.

Conversation Checklist

Who will you talk to about dying?

- ❑ Who will be involved in your care and needs to understand your wishes?
- ❑ Think about opening a conversation, or setting up an appointment to do so, with ...
  - ❑ Family members or loved ones closest to you (list them)

    _____

    _____
  - ❑ Your doctor or caregiver

    _____
  - ❑ Your pastor or spiritual advisor

    _____
  - ❑ Other people such as your attorney, hospice care provider or funeral home director

    _____

    _____

Where do you want to be when you die? Who do you want around you?

Most North Dakotans want to die at home.

- ❑ Are there services, such as hospice care, that could help you do that?
- ❑ Who do you want near you when you die? What do you want your loved ones to know?

Who do you want to make decisions for you when you can't?

You should name a "representative," someone you fully trust, who will help to see that your wishes are carried out.

- ❑ Who will be involved in your care?
- ❑ Have you talked to this person about being your representative if you are unable to make decisions?
- ❑ Does your representative understand your wishes for the end of life?
- ❑ Does your representative have a copy of your advance directive?

What kinds of medical treatment do you want or not want? What services will you need to be as comfortable as you want to be?

Discuss specific medical options with your health care provider.

- ❑ How do you feel about relying on machines to stay alive?
- ❑ Do you want everything possible to be done to prolong your life?
- ❑ What kind of "quality of life" measures, such as pain management, do you want at the end of life?
- ❑ How could hospice care help you and your family at the end of life? How can you access those services when that time comes?

... and Issues to Talk About

ONE FAMILY'S STORY ...

Dr. Hanson already knew Bill's wishes. Suffering from terminal cancer, 80-year-old Bill had told his physician he wanted no "heroic measures."

"When the time comes, just let me go," Bill said.

Near the end of Bill's life, though, his children—concerned about dehydration and nutrition—insisted on continuing IVs and oxygen.

"He was unconscious, and there was no hope he would recover," Dr. Hanson recalls. "I felt we were prolonging his suffering."

Unfortunately, the scenario is familiar to people in medicine.

"People really should talk over their wishes with their family as well as their physician," states Dr. Hanson. "If they have a document on hand, they should show that to their family, too. When people have talked to their family members, it really helps family make decisions that are what the loved one would have wished."

Hospice Care and Pain Management

Hospice care is a form of end-of-life care that focuses on enhancing the quality of life of a person's last days. Hospice care services, including medical, emotional, spiritual and grief care, help you stay as comfortable as possible and allow many people to stay in the familiar surroundings of home.

You will want to consider choosing hospice care ...

- When you want the focus to be on your comfort and the needs of you *and* your family.
- For expert help in pain and symptom management.
- When you want your loved ones to have help caring for you while you are dying.

Hospice care can have a positive impact on you and your loved ones.

When you talk about dying ...

Tell your loved ones, health care provider, spiritual advisor and others ...

- Where do you want to die? Do you want to die at home, if possible?
- Are there hospice services that will help your family care for you? How can they access them?
- What kind of help might your loved ones need if you are dying at home?
- Do you have questions about pain and symptom management?

What Forms Do You Need?

North Dakota has legal forms that you can use to help start conversations and clearly set forth your wishes, in writing, for the end of life.

These forms are called "advance directives." By using an advance directive, such as a living will or durable power of attorney for health care, you can ...

- Give instructions about any aspect of your health care.
- Choose a person to make health care decisions for you.
- Give instructions about specific medical treatments you do or do not want, including life-sustaining measures.

If in the future you are unable to communicate or make decisions, your family, physician and others will know your wishes.

Make sure you ...

- Talk beforehand to any person you wish to appoint as your representative.
- Discuss your advance directive with your representative, family, health care providers and others.
- Give each of them a copy of your signed advance directive form.

On the following pages, you will find a sample advance directive.

This form combines a living will and a durable power of attorney for health care.

TERMS TO KNOW

Advance Care Planning: Making decisions, in advance, about the care you would want to receive if you are unable to communicate or make decisions for yourself. Advance planning should be based on an understanding of your own values, personal reflections, and discussions you hold with loved ones, health care providers and others.

Advance Directive: A legal document, including a durable power of attorney for health care and/or a living will, that provides directions for your health care if you are unable to communicate or make decisions.

Living Will: Your directions to health care providers for the kinds of end-of-life treatment you do and do not want if you are terminally ill and cannot communicate or make decisions for yourself.

Durable Power of Attorney for Health Care: A document choosing someone to make health care decisions for you if you are unable to communicate or make your own decisions.

North Dakota
ADVANCE DIRECTIVE FOR MY HEALTH CARE

Print your full name _____ **Date of birth** _____

PART 1 Allows you to appoint another person (called a health care representative or "agent") to make health care decisions if you lack the capacity to do so, consistent with your representative's knowledge of your wishes and religious or moral beliefs. If you wish, you may also express your desires about your health care in this directive. If your wishes are unknown, your representative will make health care decisions that are deemed to be in your best interest.

PART 2 Allows you to complete a "living will" by expressing your wishes for the kind of medical treatment you want or do not want if you become terminally ill and your death is imminent.

PART 3 Allows you to make an organ and tissue donation upon your death, by signing a document of anatomical gift.

PART 4 Requires you and others to sign or notarize this advance directive.

This is an important legal document for completion by individuals eighteen years or older. It substantially incorporates the Durable Power of Attorney for Health Care form (Part 1) and the Living Will form (Part 2), which are two kinds of advance directives authorized in North Dakota law. Not all parts of this combined form need to be completed. You may designate a health care representative in Part 1, and not complete a living will in Part 2. You may also complete a living will in Part 2, and not designate a representative in Part 1. Or you may complete both Parts 1 and 2. The document also incorporates a document of anatomical gift (Part 3), which is optional and need not be completed if you do not wish to make an anatomical gift.

Even if you sign an advance directive, you have the right to make medical and other health care decisions for yourself so long as you can give informed consent with respect to the particular decision. If there is anything in this document that you do not understand, you should ask a lawyer to explain it to you. *You may want to consult with a lawyer regarding the legal sufficiency of your advance directive. You are also encouraged to talk with other professionals, including your physician or other health care provider, about your options.*

PART 1. MY HEALTH CARE REPRESENTATIVE

Part 1, the Durable Power of Attorney for Health Care, would authorize your representative to make health care decisions on your behalf if you lack the capacity to make health care decisions as certified in writing by your attending physician. This authority applies to all health care decisions — that is, your representative would have authority to request, consent to, refuse to consent to, or to withdraw consent for any care, treatment, service, or procedure to maintain, diagnose, or treat a physical or mental condition if you are unable to do so yourself. This power is subject to any statement of your desires and any limitation that you include in this document or otherwise make known. You may state in this document any types of treatment that you do not desire. In addition, a court can take away the power of your representative to make health care decisions for you if your representative authorizes anything that is illegal; acts contrary to your known desires; or, where your desires are not known, does anything that is clearly contrary to your best interest.

My health care representative may make **ALL** health care decisions for me as authorized in this document and shall be given access to all my medical records. This appointment, in accordance with North Dakota's Durable Power of Attorney for Health Care law (NDCC 23-06.5), applies if I lack the capacity to make health care decisions.

1. **DESIGNATION OF HEALTH CARE REPRESENTATIVE.**
   I,_____
   (Insert your name and address.)
   appoint: _____
   (Insert name, address, and telephone number of one individual only.)
   as my attorney in fact ("representative") to make health care decisions for me as authorized in this document. My representative's authority is effective when I cannot understand and appreciate the nature and consequences of a health care decision, including the significant benefits and harms of, and reasonable alternatives to, any proposed health care. I revoke any prior appointments. *None of the following may be designated as your health care representative: your treating health care provider, a nonrelative employee of your treating health care provider, an operator of a long-term care facility, or a non-relative employee of an operator of a long-term care facility.*

2. **DESIGNATION OF ALTERNATE REPRESENTATIVES.**
   If the person designated as my representative in paragraph 1 is not available or becomes ineligible to act as my representative to make health care decisions for me or loses the mental capacity to make health care decisions for me, or if I revoke that person's appointment or authority to act as my representative to make health care decisions for me, then I designate and appoint the following persons to serve as my representative to make health care decisions for me as authorized in this document, such persons to serve in the order listed below:

   a. First Alternate: _____
   (Insert name, address and telephone number of first alternate representative.)
   b. Second Alternate: _____
   (Insert name, address and telephone number of second alternate representative.)

3. **GENERAL STATEMENT OF AUTHORITY GRANTED.** Subject to any limitations in this document, I hereby grant to my representative full power and authority to make health care decisions for me to the same extent that I could make such decisions for myself if I had the capacity to do so. In exercising this authority, my representative shall make health care decisions that are consistent with my desires as stated in this document or otherwise made

known to my representative, including my desires concerning obtaining, refusing or withdrawing life-prolonging care, treatment, services, and procedures.

4. **STATEMENT OF DESIRES, SPECIAL PROVISIONS, AND LIMITATIONS.** In exercising the authority under this advance directive, my representative must make health care decisions that are consistent with my known desires. I have decided to make the following written statement concerning my desires (a written statement is not required).

_____

_____

You may attach additional pages if you need more space to complete your statement. If you attach additional pages, you must date and sign EACH of the additional pages at the same time you date and sign this document.

5. **INSPECTION AND DISCLOSURE OF INFORMATION RELATING TO MY PHYSICAL OR MENTAL HEALTH.** Subject to any limitations in this document, my representative has the power and authority to do all of the following:
   a. Request, review, and receive any information, verbal or written, regarding my physical or mental health, including medical and hospital records.
   b. Execute on my behalf any releases or other documents that may be required in order to obtain this information.
   c. Consent to the disclosure of this information.

If you want to limit the authority of your representative to receive and disclose information relating to your health, you must state the limitations in paragraph 4 above.

6. **SIGNING DOCUMENTS, WAIVERS, AND RELEASES.** Where necessary to implement the health care decisions that my agent is authorized by this document to make, my representative has the power and authority to execute on my behalf all of the following:
   a. Documents titled or purporting to be a "Refusal to Permit Treatment" and "Leaving the Hospital Against Medical Advice."
   b. Any necessary waiver or release from liability required by a hospital or physician.

PART 2. LIVING WILL DECLARING MY WISHES IF I AM TERMINALLY ILL

I provide these directions in accordance with the North Dakota Rights of the Terminally Ill Act (NDCC 23-06.4). These directions concern life-prolonging treatment, and nutrition and hydration. *Life-prolonging treatment is any medical procedure, treatment or intervention that will only serve to prolong the process of dying and where, in the judgment of the attending physician, death will occur whether or not treatment is provided. Life-prolonging treatment does not include nutrition or hydration, or medical procedures necessary to provide comfort care or alleviate pain.* These directions in Part 2 apply only if **BOTH** of the following two conditions exist. If my attending physician and another physician determine that:

(1) I have a terminal condition (an incurable or irreversible condition that, without the administration of life-prolonging treatment, will result in my imminent death); **AND**

(2) I am no longer able to make decisions regarding administration of life-prolonging treatment.

If I have been diagnosed as pregnant and that diagnosis is known to my physician, these directions are not effective during the course of my pregnancy. I may revoke these directions at any time.

1. **LIFE-PROLONGING TREATMENT.** I have made the following decision concerning life-prolonging treatment *(initial only one statement):*

[ ] I provide no directions at this time.

[ ] I direct my attending physician to provide life-prolonging treatment, which could extend my life ~~and that I be permitted to die naturally~~. It is my intention that this declaration be honored by my family and physicians as the final expression of my legal right to direct that medical or surgical treatment be provided.

[ ] I direct my attending physician to withdraw or withhold life-prolonging treatment that would serve only to prolong the process of my dying, and that I be permitted to die naturally. It is my intention that this declaration be honored by my family and physicians as the final expression of my legal right to refuse medical or surgical treatment and that they accept the consequences of that refusal, which is death.

2. **HYDRATION / FLUIDS.** I have made the following decision concerning the administration of fluids when my death is imminent *(initial only one statement):*

[ ] I provide no directions at this time.

[ ] If I cannot drink, I want to receive fluids.

[ ] If I cannot drink, I want to receive fluids, unless I cannot physically assimilate fluids, fluids would be physically harmful or would cause unreasonable physical pain, or fluids would only prolong the process of my dying.

[ ] If I cannot drink, I do not want to receive fluids.

3. **NUTRITION / FOOD.** I have made the following decision concerning the administration of food when my death is imminent *(initial only one statement):*

[ ] I provide no directions at this time.

[ ] If I cannot eat, I want to receive food.

[ ] If I cannot eat, I want to receive food, unless I cannot physically assimilate food, food would be physically harmful or would cause unreasonable physical pain, or food would only prolong the process of my dying.

[ ] If I cannot eat, I do not want to receive food.

Concerning the administration of food and fluids, I understand that if I make no statement about food or fluids, my attending physician may withhold or withdraw food or fluids if the physician determines that I cannot physically assimilate food or fluids or that food or fluids would be physically harmful or would cause unreasonable physical pain.

4. **STATEMENT OF ADDITIONAL DESIRES AND LIMITATIONS.**

[ ] I have these additional directions:

_____

_____

You may attach additional pages if you need more space to complete your statement. If you attach additional pages, you must date and sign EACH of the additional pages at the same time you date and sign this document.

PART 3. DOCUMENT OF ANATOMICAL GIFT

I, _____, would like to be an organ donor at the time of my death. I have told my family my decision and ask my family to honor my wishes. I wish to donate the following *(initial one statement)*:

[ ] any needed organs, tissue or other body parts.

[ ] only the following organs, tissue or other body parts: _____

_____

PART 4. SIGNATURES

1. YOUR SIGNATURE

I sign my name to this document on _____(Date) at _____(City), _____ (State).

_____
You sign here

THIS DIRECTIVE WILL NOT BE VALID UNLESS IT IS NOTARIZED OR SIGNED BY TWO QUALIFIED WITNESSES WHO ARE PRESENT WHEN YOU SIGN OR ACKNOWLEDGE YOUR SIGNATURE. IF YOU HAVE ATTACHED ANY ADDITIONAL PAGES TO THIS FORM, YOU MUST DATE AND SIGN EACH OF THE ADDITIONAL PAGES AT THE SAME TIME YOU DATE AND SIGN THIS DIRECTIVE.

IF YOU ARE A RESIDENT OF A LONG-TERM CARE FACILITY, OR IF YOU ARE A PATIENT IN A HOSPITAL OR BEING ADMITTED TO A HOSPITAL, YOU SHOULD CONSULT WITH A FACILITY OR HOSPITAL REPRESENTATIVE REGARDING THE NEED FOR ANY ADDITIONAL STATEMENTS OR SIGNATURES.

2. THE SIGNATURE OF YOUR HEALTH CARE REPRESENTATIVE TO ACCEPT APPOINTMENT (if appointed under Part 1)

I accept this appointment and agree to serve as representative for health care decisions. I understand I have a duty to act consistently with the desires of the principal as expressed in this appointment. I understand that this document gives me authority over health care decisions for the principal only if the principal becomes incapable. I understand that I must act in good faith in exercising my authority under this power of attorney. I understand that the principal may revoke this power of attorney at any time in any manner. If I choose to withdraw during the time the principal is competent, I must notify the principal of my decision. If I choose to withdraw when the principal is incapable of making the principal's health care decisions, I must notify the principal's physician.

_____
Signature of representative/date

_____
Signature of alternate representative/date

3. SIGNATURES OF WITNESSES OR NOTARY (required)

This document must be notarized **OR** witnessed by two qualified adult witnesses. The person notarizing this document may be an employee of a health care or long-term care provider providing your care. At least one witness must not be a health care or long-term care provider providing you with direct care or an employee of the health care or long-term care provider providing you with direct care. None of the following may be used as a notary or witness: (1) A person you designate as your agent or alternate agent; (2) Your spouse; (3) A person related to you by blood, marriage, or adoption; (4) A person entitled to inherit any part of your estate upon your death; (5) A person who has, at the time of executing this document, any claim against your estate; (6) Your attending physician; or (7) A person directly financially responsible for your medical care.

Choose either option 1 ***OR*** *option 2 below:*

Option 1: Notary Public

In my presence on _____ (date), _____ (name) acknowledged his/her signature on this document or acknowledged that he/she directed the person signing this document to sign on his/her behalf.

_____

(Signature of Notary Public) My commission expires_____, 20__.

Option 2: Two Witnesses

Witness One:

(1) In my presence on _____ (date), _____ (name) acknowledged his/her signature on this document or acknowledged that he/she directed the person signing this document to sign on his/her behalf.

(2) I am at least eighteen years of age.

(3) If I am a health care provider or an employee of a health care provider giving direct care to the principal, I must initial this box: [ ].

I certify that the information in (1) through (3) is true and correct.

_____ _____

(Signature of Witness One) (Address)

Witness Two:

(1) In my presence on _____ (date), _____ (name) acknowledged his/her signature on this document or acknowledged that he/she directed the person signing this document to sign on his/her behalf.

(2) I am at least eighteen years of age.

(3) If I am a health care provider or an employee of a health care provider giving direct care to the principal, I must initial this box: [ ].

I certify that the information in (1) through (3) is true and correct.

_____ _____

(Signature of Witness Two) (Address)

Attachment 2a

NORTH DAKOTA

POLICIES EVALUATED

Statutes

UNIFORM CONTROLLED SUBSTANCES (*No provisions found*)
Title 19. Food, Drugs, Oils and Compounds; Chapter 19-03.1. Uniform Controlled Substances Act

MEDICAL PRACTICE ACT (*No provisions found*)
Title 43. Occupations and Professions; Chapter 43-17. Physicians and Surgeons

PHARMACY PRACTICE ACT (*No provisions found*)
Title 43. Occupations and Professions; Chapter 43-15. Pharmacists

INTRACTABLE PAIN TREATMENT ACT (*Part of the Controlled Substances Act*)
Title 19. Food, Drugs, Oils and Compounds; Chapter 19-03.3. Controlled Substances for Care & Treatment; Sections 19-03.3-01 – 19-03.3-06

Regulations

CONTROLLED SUBSTANCES REGULATIONS
No policies found

MEDICAL BOARD REGULATIONS (*No provisions found*)
Title 50. Board of Medical Examiners

PHARMACY BOARD REGULATIONS
Title 61. Board of Pharmacy

Other Governmental Policies

No policies found

NORTH DAKOTA

PROVISIONS THAT MAY ENHANCE PAIN MANAGEMENT

	1	2	3	4	5	6	7	8
Criteria	**Controlled substances are necessary for public health**	**Pain management is part of medical practice**	**Opioids are part of professional practice**	**Encourages pain management**	**Addresses fear of regulatory scrutiny**	**Prescription amount alone does not determine legitimacy**	**Physical dependence or analgesic tolerance are not confused with "addiction"**	**Other provisions that may enhance pain management**
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act		•	•		•			•
REGULATIONS								
Controlled Substances[2]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy
[2] No policy found

NORTH DAKOTA

PROVISIONS THAT MAY IMPEDE PAIN MANAGEMENT

	9	10	11	12	13	14	15	16	17
Criteria	**Opioids are a last resort**	**Implies opioids are not part of professional practice**	**Perpetuates belief that opioids hasten death**	**Physical dependence or analgesic tolerance confused with "addiction"**	**Medical decisions are restricted**	**Length of prescription validity is restricted**	**Practitioners are subject to additional prescription requirements**	**Other provisions that may impede pain management**	**Provisions that are ambiguous**
STATUTES									
Controlled Substances Act[1]									
Medical Practice Act[1]									
Pharmacy Practice Act[1]									
Intractable Pain Treatment Act		•			•				•
REGULATIONS									
Controlled Substances[2]									
Medical Board[1]									
Pharmacy Board									•
OTHER GOVERNMENTAL POLICIES[1]									

Note: A dot indicates that one or more provisions were identified

[1] No provisions were found in this policy

[2] No policy found

NORTH DAKOTA

STATUTES

Intractable Pain Treatment Act

Section 19-03.3-01.
As used in this chapter, unless the context otherwise requires:
1. "Board" means the state board of medical examiners.
2. "Intractable pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.
3. "Physician" means a physician licensed by the board.

Section 19-03.3-02.
Notwithstanding any other provision of law, a physician may prescribe or administer controlled substances to a patient in the course of the physician's treatment of the patient for intractable pain. A physician shall keep records of purchases and disposals of controlled substances prescribed or administered under this section. The records must include the date of purchase, the date of sale or administration by the physician, the name and address of the patient, and the reason for the prescribing or the administering of the substances to the patient.

Section 19-03.3-03.
No hospital or health care facility may forbid or restrict the use of controlled substances when prescribed or administered by a physician having staff privileges at that hospital or health care facility for a patient diagnosed and treated by a physician for intractable pain.

Section 19-03.3-04.
The board may not discipline a physician for prescribing or administering controlled substances in the course of treatment of a patient for intractable pain under this chapter.

Section 19-03.3-05.
This chapter does not apply to a person being treated by a physician for chemical dependency because of the person's use of controlled substances. This chapter does not authorize a physician to prescribe or administer controlled substances to a person the physician knows is using controlled substances for nontherapeutic purposes. A person to whom controlled substances are prescribed or administered for intractable pain is not exempt from section 39-08-01 or 39-20-04.1.

Section 19-03.3-06.
This chapter does not limit the authority of the board to cancel, revoke, or suspend the license of any physician who:
1. Prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed.
2. Fails to keep complete and accurate records of purchases and disposals of controlled substances listed in chapter 19-03.1.
3. Writes false or ficticious prescriptions for controlled substances scheduled in chapter 19-03.1.

CRITERION 10: [-]
Implies opioids are not part of professional practice

CRITERION 2: [+]
Pain management is part of medical practice

CRITERION 5: [+]
Addresses fear of regulatory scrutiny

CRITERION 13a: [-]
Medical decisions are restricted (Restrictions based on patient characteristics)

CRITERION 17: [-]
Provisions that are ambiguous

Comment: Does this imply that opioids are a treatment of last resort?

CRITERION 3: [+]
Opioids are part of professional practice

CRITERION 8: [+]
Other provisions that may enhance pain management

Comment: This provision attempts to provide for a secure environment for physicians prescribing in their healthcare facility. However, this only applies to prescribing for intractable pain patients and not patients in general.

REGULATIONS

Pharmacy Board Regulations

N.D. Admin. Code 61-04-04-01

61-04-04-01. Definition of unprofessional conduct

The definition of "unprofessional conduct" for purposes of subdivision i of subsection 1 of North Dakota Century Code section 43-15-10 for disciplinary purposes includes, but is not limited to, the following:

.
.
.

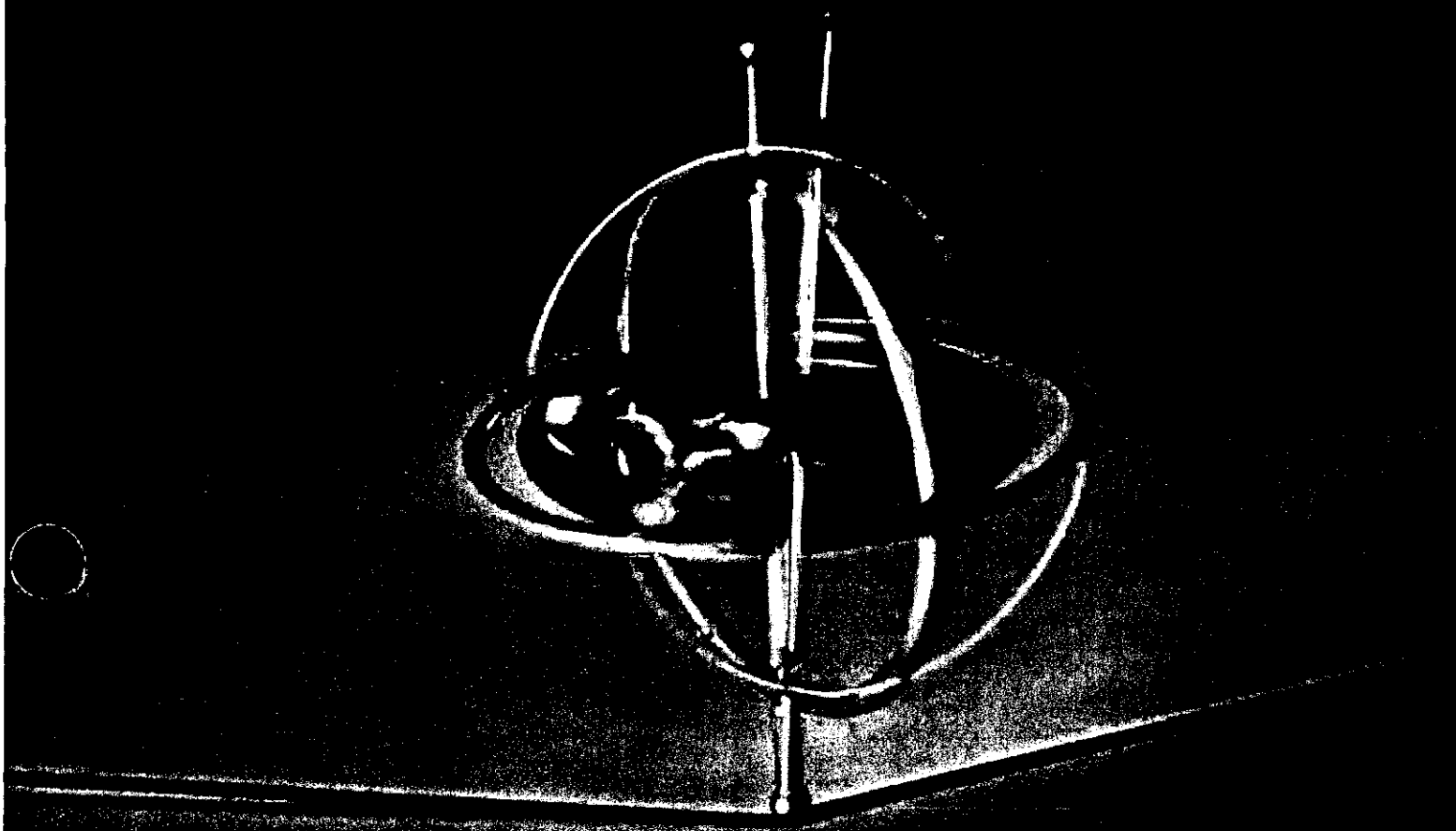
11. Does not attempt to affect the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, if there is reason to believe that patient may be so dependent or addicted.

.
.
.

CRITERION 17: [-]
Provisions that are ambiguous

Comment: It is unclear what actions are expected of the pharmacist to "attempt to affect" a patient who may be addicted or dependent on a drug.

ACHIEVING BALANCE
in Federal & State Pain Policy:
A Guide to Evaluation, Second Edition



Pain & Policy Studies Group
University of Wisconsin
Comprehensive Cancer Center
www.medsch.wisc.edu/painpolicy

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Attachment 2b

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Federation of State Medical Boards of the United States, Inc.

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., May 2004.

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The *Model Guidelines* have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the *Model Guidelines*.[1] Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life.[2] The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies.[3] Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

In April 2003, the Federation membership called for an update to its *Model Guidelines* to assure currency and adequate attention to the undertreatment of pain. The goal of the revised model policy is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document.

The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of

regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain as well as to update references and definitions of key terms used in pain management.

The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

1. As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* and two (2) states have formally endorsed the *Model Guidelines*.
2. SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: *JAMA*, 274(20) (1995): p. 1591-1598.
3. A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31 (2003): p. 128.

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a

legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

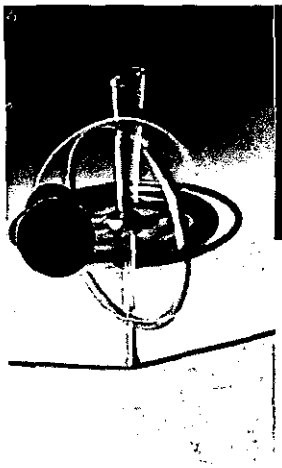
Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.



INTRODUCTION

Unrelieved pain continues to burden Americans

It is well documented that unrelieved pain continues to be a serious public health problem for the general population in the United States.[1-8] This issue is particularly salient for children,[9-12] the elderly,[13-15] minorities,[16-20] patients with active addiction or a history of substance abuse,[21-23] developmental disabilities,[24] as well as for those with serious diseases such as cancer,[25-27] HIV/AIDS,[10,28,29] or sickle cell disease.[30] Clinical experience has demonstrated that adequate pain management leads to enhanced functioning and increased quality of life, while uncontrolled pain contributes to disability and despair.

Pain can be relieved

There are many safe and effective drug and non-drug ways to manage pain, which vary according to the individual needs of the patient. However, there is a general medical and regulatory consensus that opioid[a] analgesics are necessary to maintain public health;[31] they often are the mainstay of treatment, particularly if pain is severe.[25,27,32,33] Their use for the relief of a variety of chronic non-cancer pain conditions is also clinically beneficial, although more studies are needed to guide selection of patients and use of opioids.[34,35]

The gap

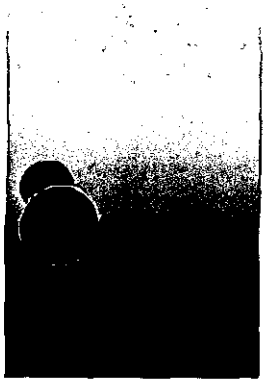
Although medical science has learned a great deal about pain management in the last 20 years, not all of this knowledge has been incorporated into practice. Consequently, a gap exists between what is known about the medical management of pain and the actual practices of caregivers and healthcare institutions. Incomplete or inaccurate knowledge, and varying attitudes about pain and the use of opioid medications, can inhibit pain management.

Influence of drug abuse control policy

Opioid medications have a potential for abuse. Consequently, they and the healthcare professionals who prescribe, administer, or dispense them are regulated pursuant to federal and state controlled substances policies, as well as under state laws and regulations that govern professional practice.[36] Such policies are intended only to prevent drug abuse and substandard practice related to prescribing, but in some cases go well beyond the usual framework that governs controlled substances and professional practice policy and can negatively affect legitimate medical practices and create undue burdens on caregivers and patients.[37]

Some state policies do not conform to, or conflict with, current standards of professional practice, by:

- limiting the amounts that can be prescribed and dispensed,
- requiring special government-issued prescription forms,
- restricting access to patients who have a history of substance abuse or with addictive disease, even if they also have pain,



[a] The term opioid refers to natural and semi-synthetic derivatives of the opium poppy, as well as similar synthetic compounds that have analgesic or pain relieving properties because of their effects in the central nervous system. These include codeine, morphine, hydromorphone, hydrococone, oxycodone and fentanyl. Opioids are often inappropriately referred to as narcotics, a legal term that is no longer used in medicine because it suggests that opioids relieve pain by inducing sedation; while sedation can be a side effect of opioids it is not the mechanism that produces pain relief.

- using outdated language that confuses pain patients with people who have addictive disease,
- considering opioids to be a treatment of last resort, and
- suggesting that therapeutic use of opioids may hasten death.

In addition to the presence of potentially restrictive language, language that can enhance pain management is frequently absent from state policies. For example, some states do not recognize that controlled substances are necessary for the public health or that pain management is an integral part of the practice of medicine, which are policies that have been recommended by governmental authorities in controlled substances and medical practice policy.[31,37-40]

The need to evaluate policy

International and national authorities, including the World Health Organization (WHO), the International Narcotics Control Board (INCB), the Institute of Medicine (IOM), the American Cancer Society (ACS), and the National Institutes of Health (NIH), have called attention to the inadequate treatment of pain and have concluded that it is due in part to drug abuse control policies that impede medical use of opioids.[b] These authorities have recommended evaluation and improvement of pain policies. For example, following a review of the reasons for inadequate cancer pain relief, the INCB asked all governments in the world to:

> *"...examine the extent to which their health-care systems and laws and regulations permit the use of opiates for medical purposes, identify possible impediments to such use and develop plans of action to facilitate the supply and availability of opiates for all appropriate indications"* (p. 17).[41]

The WHO has stated that better pain management could be achieved throughout the world if governments used evaluation guidelines to identify and overcome regulatory barriers to the availability and appropriate medical use of opioid analgesics.[32]

In the U.S., the IOM Committee on Opportunities in Drug Abuse Research called for:

> *"...additional research on the effects of controlled substance regulations on medical use and scientific research. Specifically, these studies should encompass the impact of such regulations and their enforcement on prescribing practices and patient outcomes in relation to conditions such as pain...[and]... for patients with addictive disorders" (p. 259).*[42]

The IOM Committee on Care at the End of Life recommended:

> *"...review of restrictive state laws, revision of provisions that deter effective pain relief, and evaluation of the effect of regulatory changes on state medical board policies..." [and] "reform [of] drug prescription laws, burdensome regulations, and state medical board policies and practices that impede effective use of opioids to relieve pain and suffering" (p. 198, 267).*[2]

The ACS recently stated that

> *"...additional and sustained efforts are needed to ensure that new barriers are not erected and that adequate pain relief for cancer patients is assured"* (p. 3).[43]

An NIH expert panel concluded that

> *"Regulatory barriers need to be revised to maximize convenience, benefit, and compliance..."* (p. 15).[5]

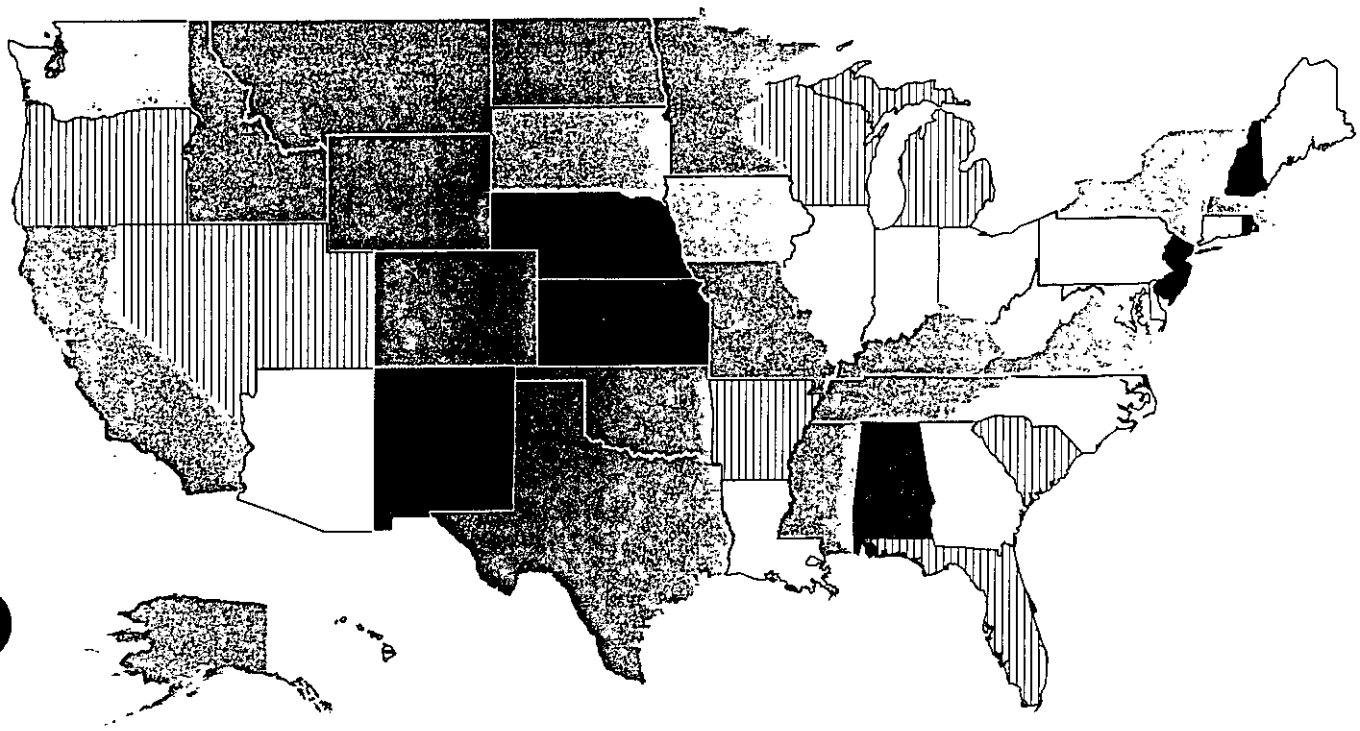
[b] The Agency for Healthcare Policy and Research is not included as an authoritative source because its clinical practice guidelines on acute pain (1992) and cancer pain (1994) have been withdrawn.

MAKING THE GRADE: HOW DO THE STATES RATE?

Grades for 2003

Figure 1:

States' grades for 2003 are presented in Figure 1 and Table 5.



A	B+	B	C+	C	D+	D	F
None	Alabama	Iowa	Arkansas	Alaska	Arizona	New Hampshire	None
	Kansas	Maine	Florida	California	Connecticut	New Jersey	
	Nebraska	North Carolina	Maryland	Colorado	Delaware	Rhode Island	
	New Mexico	Pennsylvania	Michigan	Connecticut	Dist. of Columbia		
		South Dakota	Nevada	Idaho	Georgia		
		Washington	Oregon	Massachusetts	Hawaii		
		West Virginia	South Carolina	Minnesota	Illinois		
			Utah	Mississippi	Indiana		
			Wisconsin	Missouri	Louisiana		
				Montana	Ohio		
				New York			
				North Dakota			
				Oklahoma			
				Tennessee			
				Texas			
				Vermont			
				Virginia			
				Wyoming			

Attachment 4

TO: HUMAN SERVICES COMMITTEE

FROM: ROLF SLETTEN, EXECUTIVE SECRETARY

RE: SB 2166

DATE: JANUARY 19, 2005

We have told the Medical Association that we will not object to the change in the definition of "pain". That definition, I think, is the main focus of this bill. We are not objecting to that change.

We are concerned about the language in the last section, line 16 and 17. This bill states that:

"This chapter does not authorize a physician to prescribe or administer controlled substances for pain to a person the physician knows is using those controlled substances for nontherapeutic purposes".

The Medical Practice Act (§43-17-31(17)) already prohibits a physician from prescribing or administering "any drug legally classified as a controlled substance or as an addictive or dangerous drug for other than medically accepted therapeutic purposes".

This bill would leave us with two standards that are almost exactly the same (they both talk about prescribing for nontherapeutic purposes) but not quite the same. That inevitably leads to questions and arguments. Those arguments can lead to appeals. Appeals are expensive and time consuming. This language is confusing. Inevitably someone will ask:

North Dakota Board of Medical Examiners
January 19, 2005

PROPOSED AMENDMENTS TO SENATE BILL NO. 2166

Page 2, line 16, overstrike "controlled substances for pain" and insert immediately thereafter "any drug legally classified as a controlled substance or as an addictive or dangerous drug for"

Page 2, line 17, overstrike "to a person the physician knows is using those controlled substances for nontherapeutic" and replace with "other than medically accepted therapeutic"

Attachment 5

ND Medical Association
ND Board of Medical Examiners
January 25, 2005

PROPOSED AMENDMENTS TO SB 2166

Page 1, line 7, overstrike "a pain state"

Page 1, line 10, after "~~efforts~~" insert "acute pain and chronic pain. Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease, and is generally time-limited. Chronic pain is a state"

Page 2, line 15, after "substances" insert "not related to treatment for pain"

Page 2, line 16, overstrike "controlled substances" and replace "for pain" with "any drug legally classified as a controlled substance or as an addictive or dangerous drug for other than medically accepted therapeutic purposes"

Page 2, line 17, overstrike "to a person the physician knows is using", remove "those", and overstrike "controlled substances for nontherapeutic"

Page 2, line 18, overstrike "purposes"

Renumber accordingly

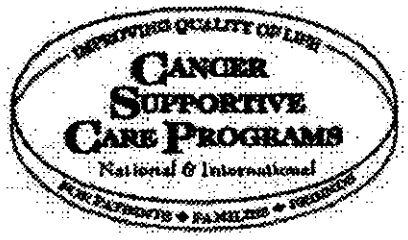
NOTE

With these proposed amendments, the definition of "pain" would track the definitions used by the Federation of State Medical Boards' new policy for acute pain and chronic pain, and would read:

"Pain" means acute pain and chronic pain. Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease, and is generally time-limited. Chronic pain is a state that persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

The section 5 application section would incorporate the ND Board of Medical Examiners' proposed amendments and clarify application to persons with chemical dependency, and would read:

19-03.3-05. Application. This chapter does not apply to a person being treated by a physician for chemical dependency because of the person's use of controlled substances not related to treatment for pain. This chapter does not authorize a physician to prescribe or administer ~~controlled substances to a person the physician knows is using controlled substances for nontherapeutic purposes~~ any drug legally classified as a controlled substance or as an addictive or dangerous drug for other than medically accepted therapeutic purposes. A person to whom controlled substances are prescribed or administered for ~~intractable~~ pain is not exempt from section 39-08-01 or 39-20-04.1.



Fifth Dimension Table of Contents

Pain Control

Wendy Robbins, MD; Robert W. Allen, MD

Pain

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Many patients with cancer fear that they will suffer pain. In fact, at some point during the course of the disease, 60 to 90 percent of patients will require a pain-relieving therapy. But not all cancers produce pain equally, and some cancers, even when advanced, may not cause pain at all. Cancers that are more typically painful include tumors of the bone (either primary or through spread) and the organs of the abdomen. Cancers of the blood system, such as leukemias or lymphomas, often never cause pain.

Pain can have a terrible effect on a cancer patient's life. It can lead to depression, loss of appetite, irritability, and withdrawal from social interaction, anger, loss of sleep and an inability to cope. If uncontrolled, pain can destroy relationships with loved ones and the will to live. Fortunately, pain can almost always be controlled. What is needed is an understanding by caregivers of the nature of the pain, of what causes it and of the appropriate treatments for the type of pain involved, as well as a commitment to relieving it. The oncologist is usually well equipped to handle most types of pain. For more unremitting pains, patients may be referred by their doctor to a specialist who will help to sort out the cause and treatments for symptoms.

Pain is a complex phenomenon. It has physical, emotional and psychological components. How each person responds to pain is also complex. The extent of disease and the nature of the discomfort contribute to a person's experience of pain. But pain is also modified by remembrances of past painful episodes, the special meaning of pain to each individual, the expectations of family and friends, religious upbringing and personal coping skills and strategies. Cultural beliefs also influence the pain experience. Certain cultures teach tolerance of pain or that the outward expression of pain is inappropriate. People from these cultures bear their pain without complaining or even expressing their needs. Externally, they may appear to have a higher threshold or tolerance to pain while in fact suffering quietly. Other cultures readily and outwardly express painful experiences, and people from those cultures may appear to have a lower threshold or tolerance.

Types of Pain

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Somatic Pain from the cancer itself may come from a bone broken because of tumor

invasion or from an obstruction in the intestine or urinary tract. Pain from bone involvement is often described as achy, dull, localized and brought about by activity of the surrounding muscle groups or movement of the limb or spine. Obstructions in the intestine or urinary tract typically are described as crampy and more diffuse. They may be associated with inability to eat or to pass stool or urine.

Neuropathic Pain from nerve involvement is either related to direct tumor spread, such as the spread of colon cancer into the pelvis where the nerves to the legs or pelvic structures reside, or is secondary to irritating substances that tumors secrete near nerves. Neuropathic pain may also result from pressure on the nerves, as when spinal tumors pinch or press on nerves to the arms or legs. Neuropathic pain is often described as sharp, burning, electrical, shooting or buzzing. It typically occurs in the area that the injured nerves serve.

Surgery may cause both somatic and neuropathic pain. Pain from direct surgical injury is somatic and usually responds to opioid medications. Surgical injury to nerves may respond to opioids, antiseizure or antidepressant medications.

Chemotherapeutic drugs act like poisons to tumors and may act the same way on some vulnerable nerves. Drugs such as antiviral agents or vincristine, cisplatin, carboplatin, Taxol and Navelbine can cause peripheral neuropathy, which is often felt as a burning in the hands and feet. This requires drugs specific for neuropathic pain or some other intervention for relief. The sore mouth (mucositis) that is sometimes a side effect of these drugs is one example of somatic pain from chemotherapy.

After radiation therapy, pain may be due to skin reactions to the radiation, breakdown of mucous membranes or even scarring of the nerves (fibrosis), which can produce a neuropathic pain.

Emotional Sources

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Pain is made worse by worry and fear of death, suffering, deformity, financial disability or isolation. The onset of pain or a new pain may trigger fears about the spread of the disease or of impending death. All these fears can be magnified when a kind of spiritual pain accompanies the fear. This might be triggered by surroundings, low levels of emotional support or feelings of loneliness and desperation. How one approaches the problems of life makes a big difference to the perception of pain. Also, whether pain is adequately controlled makes a big difference.

Treatment Plan for Pain

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Treating and controlling pain is a primary concern for all members of the health care team, including your doctors, nurses and the hospital and home care team. According to the World Health Organization committee on cancer pain, 90 to 95 percent of all cancer pain can be well controlled using a special set of guidelines. These guidelines separate pain into levels of intensity and suggest tailoring the strength and potency of prescribed pain-relieving medications to the intensity. Not all cancer pain requires strong narcotics. But strong pain requires strong medications.

The guidelines suggest that

- **mild** pain be treated with nonnarcotic medications such as aspirin, acetaminophen (Tylenol) or other aspirin-like drugs called nonsteroidal anti-inflammatory drugs (NSAIDs);
- **moderate** pain be treated with a combination of NSAIDs and weak narcotics such as codeine (Tylenol with codeine), hydrocodone (Vicodin or Lortab), Percocet, Percodan or propoxyphene (Darvon), and
- **severe** pain be treated with strong opioids such as morphine, Demerol, Dilaudid, fentanyl (duragesic patches) or methadone in combination with an NSAID.

The guidelines also suggest adding an adjuvant medication to these narcotic and nonnarcotic medications when appropriate. These medications--which include steroids, bone-forming, antidepressant and anticonvulsant medications, antihistamines and sedatives--are often useful in treating opioid-resistant pain. For whatever reason, they do relieve pain, although they are not usually labeled as pain relievers.

Simple measures such as aspirin or Tylenol, with or without codeine, or ibuprofen may do the job well enough. But when pain is severe, the dosage has to be increased or the drug has to be taken more frequently. If these simple measures don't help, then it is important to increase the strength or potency of the medication. Sometimes, just the addition of an adjuvant medication is all that is needed.

Side Effects of Pain Medications

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Not all people tolerate all drugs equally. Some people are allergic to various medications. Some develop side effects from medications that others taking the same drugs do not share. Some people tolerate one specific drug in a class of drugs but do not tolerate others in the same class. Some do not tolerate any drugs in a particular class. Everyone is an individual.

While 90 to 95 percent of patients receive adequate pain control using the WHO guidelines, there are still 5 to 10 percent of patients who do not achieve adequate pain control. Certain direct interventions by specialists can modify or block pain information from reaching the central nervous system. These interventions include nerve blocks with local anesthetics or nerve-destroying agents, alternative delivery systems such as administering narcotics under the skin (subcutaneous) or into the spine, spinal local anesthetics or other therapies that destroy nerves causing the pain. These invasive, interventional therapies require the expertise and skills of a pain specialist. Morphine remains the gold standard of medical practice. Morphine and other options can be taken in a variety of ways. Most methods control pain very effectively.

Myths about Narcotics and Cancer Pain Control

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A lot of cancer patients want to avoid taking opioids. Many fear that they will become addicted to these medications, and some feel that narcotics should be used only as a last resort for fear that they will not be effective when they are really needed. Doctors may also share some of the myths about opioid medications. These myths form barriers to good and effective relief of cancer pain. These myths need to be understood and addressed by patients and their caregivers.

- **Myth 1**. People given opioids for pain control are always doing worse or are near

death.

Just because a person is placed on a narcotic does not mean that he or she is gravely ill. Opioids are highly effective medications that can be used at any stage in the disease when severe pain requires strong medication.

- **Myth 2**. All patients getting morphine or other opioids will become addicts.

  Addiction is a psychological need for a drug and rarely, if ever, develops in people using narcotics for pain control. Physical dependence, however, always occurs in patients taking narcotics for a long time. Physical dependence is a problem only when a patient is suddenly taken off the drug. If this happens, a physical reaction, called withdrawal syndrome, takes place. If a disease becomes cured during therapy and opioid medications are no longer needed, they can be withdrawn slowly so that the withdrawal syndrome does not develop. (However, sometimes chronic opioid medications are still needed, because of the previous tissue destruction that the tumor or therapy caused.) The bottom line is that physical dependence does not equal addiction.

- **Myth 3**. Patients who take opioid medications develop tolerance and always need more and more medicine.

  There are many reasons behind the need for increased doses of an opioid medication. One is spreading disease or a change in the type of pain, such as a new neuropathic pain problem developing with tumor spread. Another reason is tolerance, which means the need for an increasing dose of a drug in order to achieve a desired result. Tolerance, if it develops at all, does not develop suddenly, and doctors can respond to its development by increasing the dose. Opioid medications are safe even at very high doses if given correctly. If a patient no longer experiences pain relief at one dose level, the dose can be safely increased again and again.

- **Myth 4**. Opioids are dangerous because they can make breathing harder for a terminally ill patient.

  Morphine and other opioid drugs are not dangerous respiratory depressants in patients with cancer and pain. Doses are gradually increased and tolerance to the respiratory-depressant effects of these drugs usually develops before tolerance to their pain-relieving effects.

- **Myth 5**. People taking opioids must get it by injection since opioids are poorly absorbed by mouth.

  Most opioids are absorbed very well when taken orally. However, a fair amount of the dose taken by mouth is "lost" to nontarget body tissues and therefore wasted, so larger dosages of the drug are required than the doses needed for shots. The pain equivalency between oral and intramuscular (shots) or intravenous morphine is 3 to 1 when taken over time, meaning that 30 mg of oral morphine is equivalent to 10 mg of intramuscular or intravenous morphine.

Supportive Techniques for Pain Control

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It is important to look after the emotional and psychological components of pain too. Psychological counseling can help in many ways: finding sources of emotional support, reducing any sense of loneliness and isolation, and coming to terms with your situation or planning for the future. Talking with clergy or other trusted spiritual advisers may also reduce anxieties and fears that contribute to your pain.

Anything that helps you relax can help your efforts at pain control. Relaxation exercises, massage, transcutaneous nerve stimulation, biofeedback, acupuncture and acupressure may all be of help.

Perhaps surprisingly, one very effective pain control device may be as close as your stereo. Music has been rated to have an analgesic effect twice that of a plain background sound. So listen to your favorite musical works and artists. Music can help you relax, raise your spirits, give you great joy--and help you control your pain.

Pain and Symptom Management Consultants

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Wendy Robbins, MD, Pamela Pierce Palmer, Ph.D., MD, David Lee, MD, Donna Johnson-Harvey, MD, Michael Rowbotham, MD, Dorothy Waddell, MD and Howard Fields, Ph.D., MD

The mission

Fatigue is a subjective symptom characterized by feelings of weariness and lack of energy. Fatigue is a common complaint in cancer patients, and may cause a considerable decrease in quality of life. Despite the fact that fatigue is probably the single most common unrelieved symptom of cancer (reported in up to 95% of patients at some point in their illness?), medical interventions are frequently few and inadequate. The experience of fatigue is unique for each individual, and may include social withdrawal, change in sleep patterns, change in appetite, decreased ability to handle stress, and depression.

The UCSF/Mt. Zion Pain and Symptom Management Group is a team of dedicated clinician-scientists with specialties in anesthesiology, neurology, neuropsychiatry, physical therapy, and internal medicine. We have designed a supportive care program for patients suffering pain or fatigue associated with cancer or in response to radiation therapy, surgery, chemotherapy, or immunotherapy. Interventions are individualized to each patient including medications, exercise, behavioral and psychotherapy.

> We can be contacted at the UCSF/Mt. Zion Pain Management Center:
> Phone 415-885-7246, and Fax: 415-885-7575.
> http://mountzion.ucsfmedicalcenter.org/pain_management/
> New patient evaluations are scheduled upon referral by treating physicians.

Meyerowitz, BE, Sparks, FC, Spears, IK. Adjuvant Chemotherapy for breast carcinoma: psychosocial implications. Cancer 1979, 43(5), 1613-8.

Nerenz, DR, Leventhal H, Love RR. Factors contributing to emotional distress during cancer chemotherapy. Cancer 1982, 50(5), 1020-7.

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Testimony in Support of Senate Bill No. 2166 -- Pain Management
House Human Services Committee
February 28, 2005

Madam Chairman, Members of the House Human Services Committee, I'm Bruce Levi representing the North Dakota Medical Association. The Association is the professional membership organization for physicians, residents and medical students in North Dakota, with 1,075 members.

The North Dakota Medical Association supports Engrossed Senate Bill No. 2166, and the intent of the measure to strengthen state policy encouraging adequate treatment for pain. SB 2166 passed the Senate by a vote of 45-0.

It is well documented that unrelieved pain continues to be a serious public health problem for the general population in the United States. This issue is particularly relevant for children, the elderly, minorities, patients with active addiction or a history of substance abuse, developmental disabilities, as well as for those with serious diseases such as cancer, HIV/AIDS, or sickle cell disease. Clinical experience has demonstrated that adequate pain management leads to enhanced functioning and increased quality of life, while uncontrolled pain contributes to disability and despair. There are many safe and effective drug and non-drug ways to manage pain, which vary according to the individual needs of the patient. However, there is a general medical and regulatory consensus that opioid analgesics are necessary to maintain public health; they often are the mainstay of treatment, particularly if pain is severe.

Many states, beginning with Texas in 1989, adopted legislation called "Intractable Pain Treatment Acts" or "IPTAs" in an effort to address inadequate pain management. North Dakota adopted its IPTA in 1995. The legislation was sponsored by Senator Jack Traynor and passed unanimously in the Senate and by a vote of 94-1 in the House. The main goal of these laws is to address physician reluctance to prescribe opioids for the treatment of chronic pain, due to their concern about regulatory scrutiny, by providing protection from discipline by state medical boards. State medical boards have taken additional steps in many parts of the country to improve

pain management, including clarification of policy to address physician reluctance to prescribe. In fact, original guidelines adopted by the Federation of State Medical Boards in 1998 were adopted in whole or in part by 24 state medical boards. These guidelines told physicians they need to view pain management as important and integral to the practice of medicine.

The Federation of State Medical Boards adopted a new policy in May 2004 -- *Model Policy for the Use of Controlled Substances for the Treatment of Pain* – and a copy of that new policy is included in your handouts. That policy communicates the following message to physicians, if adopted by the state medical board:

> *That the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physician have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes.*

SB 2166 would update North Dakota's "Intractable Pain Treatment Act," Chapter 19-03.3 of the North Dakota Century Code. Section 1 of the bill would incorporate definitions of "chronic pain" and "acute pain" used by the Federation of State Medical Boards in the *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Other language in the current law would be amended to use the term "pain" rather than "intractable pain," consistent with the new definition. In addition, section 5 of the bill would narrow current language that restricts medical decisions in cases involving a patient who a physician knows is using controlled substances for nontherapeutic purposes. That language is proposed to be narrowed to better reflect current pain management practices that recognize that patients with active addictive disorder or a substance abuse history are at increased risk of receiving inadequate pain management. At the same time, language was added at the request of the North Dakota Board of Medical Examiners to restate the current language in NDCC Section 43-17-31(17) allowing for discipline for the prescription, sale or administration of "any drug legally classified as a controlled substance or as an addictive or dangerous drug for other than medically accepted therapeutic purposes."

Section 1: The Federation of State Medical Boards' Definition of "Pain"

Section 1 of the bill would change the definition of "intractable pain." The current definition defines "intractable pain" as a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts." This definition of pain was reviewed by the Pain & Policy Studies Group of the University of Wisconsin's Comprehensive Cancer Center in 2000 and 2003. The Group noted that the state's definition of "intractable pain" may impede pain management by implying that opioids are not a part of professional practice and that opioids are a last resort. Handouts are provided with specific information on the Pain and Policy Group's review of North Dakota's law.

It is also suggested that the current definition of "intractable pain" implies that some individuals may develop pain that cannot be treated. In addition, the Act requires that the physician "prove a negative;" that is, the physician must prove that there is not a treatable cause for the pain, or that the pain does not respond to treatment. The definition also implies that opioids are a last resort; that the law requires a physician to undertake a potentially extensive series of diagnostic and/or treatment procedures in order to qualify for protection under the statute, thereby delaying treatment.

The new proposed definition of "pain" in section 1 of the bill comes from a model policy recently approved by the Federation of State Medical Boards -- *Model Policy for the Use of Controlled Substances for the Treatment of Pain.* SB 2166 incorporates the new model policy definitions of chronic and acute pain. The Federation states in the policy that it recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins.

Section 5: Addressing Patients with Addictive Disease

Section 5 of the bill would address the application of the protection offered under chapter 19-03.3 to persons with certain characteristics, i.e., cases involving a patient with pain who a physician knows has an active addictive disorder or a substance abuse history. The Federation of

State Medical Board's new *Model Policy for Use of Controlled Substances for the Treatment of Pain* recognizes the special needs of these patients: "Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients." Texas, the first state to adopt an Intractable Pain Treatment Act in 1989, has since repealed the language restricting prescribing to patients with addictive disease.

Organizations that have produced statements of patients' rights with respect to pain treatment are in agreement with the Joint Commission on Accreditation of Healthcare Organizations which states that "all patients have the right to the appropriate assessment and management of pain." Policy statements from the American Society of Addiction Medicine recognize that these individuals present a number of challenges when they experience pain that can be relieved with opioids, but that they nonetheless can and should receive such treatment if it is medically appropriate. Individuals with current or past histories of substance abuse "should be viewed as having a concurrent illness that requires a degree of expertise for its management, and they should not forfeit their right to pain control because of this concurrent illness."

Thank you for the opportunity to address the concerns that led to the introduction of SB 2166. On behalf of North Dakota's physicians, I urge you to recommend a "Do Pass" on Engrossed SB 2166.

NORTH DAKOTA CATHOLIC CONFERENCE

Representing the Diocese of Fargo and the Diocese of Bismarck

Christopher T. Dodson
Executive Director and
General Counsel

To: House Human Services Committee
From: Christopher T. Dodson, Executive Director
Subject: Senate Bill 2166 (Treatment and Care for Pain)
Date: February 28, 2005

The North Dakota Catholic Conference supports Senate Bill 2166.

We have made great strides during the last ten years in our understanding of pain, its psychological effects, its treatment, and societal and professional attitudes toward pain and pain relief. Advances in life-sustaining treatments and advocacy for assisted suicide compelled all involved to look more closely at the subject of pain, particularly the question of why pain was too often not treated.

Legal, educational, psychological, cultural, and medical factors have contributed to the problem. During recent years, we have seen all of these factors addressed. The existing law was part of this process and Senate Bill 2166 continues this effort by updating the law.

Putting this legal and medical effort in context - and to note one contributing cultural factor – we realize that churches have a part to play. A misunderstanding of the Christian teaching about suffering has sometimes contributed to our society's hesitancy to treat pain. Christian teaching holds that people can find meaning and even peace through suffering because it joins us to Christ's redemptive suffering. Unfortunately, some have misinterpreted this teaching as equating the good that can come from suffering with pain and suffering itself and have hesitated to relieve pain under the mistaken belief that doing so would deprive a person the good that could come from suffering.

Pain, however, is not the same as redemptive suffering. Redemptive suffering is better understood as spiritual struggle, not the same as, or dependent upon pain. Pain, especially physical pain, is an evil which must be avoided and which people have a legitimate *right* to alleviate. In fact, because it can interfere with bodily peace and cognitive functioning, pain can actually prevent, rather than contribute to, any spiritual good that could come through suffering.

Senate Bill 2166 reflects a correct understanding of pain and pain treatment. Since it does not undermine or change any of the existing protections against inappropriate actions, the North Dakota Catholic Conference urges a **Do Pass** recommendation.

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