

Administrative Rules Committee

December 5, 2017

North Dakota Board of Medicine
Bonnie Storbakken, Executive Secretary

Chairman Devlin, members of the Administrative Rules Committee, my name is Bonnie Storbakken I'm executive secretary of the North Dakota Board of Medicine. Thank you for the opportunity to provide testimony regarding rules recently passed by our board.

Please accept the following responses to the questions outlined in the letter I received from Vonette Richter.

1. These rules are not the result of statutory changes made by assembly, except for the PDMP rule which was required to be implemented in 2015 legislation introduced by Representative Kaiser in HB 1149 which required licensing Boards to implement rules regarding participation in the PDMP.
2. These rules are not related to any federal statute or regulation.
3. We followed the rule making procedure as outlined in state law and summarized in the Attorney General's manual for state agencies. Specifically, we published written notice of intent to adopt these rules in all legal newspapers during the week of August 30, 2017. We held public hearing on the rules in our office on Wednesday, September 27, 2017. We held the record open for the required 10 days following the hearing for written and oral comments. The board had a meeting in October to discuss and consider the comments. Process was reviewed by the Attorney General and approved as to its Legality in an opinion dated October 27, 2017.
4. Oral comments were received at the hearing held in September from Teledoc, Sanford Health as well as Dr. Andy McLean. These comments were regarding the telemedicine rule. Oral comments were received from the Attorney General's office that were confirmed through email regarding the PDMP rule. And written comments were received on both the PDMP rule as well as the telemedicine rule. All comments were included within Packet 1 that was sent to the Legislative Council. Additionally, all comments received on the telemedicine rule from the 2015 rulemaking process were also submitted.
5. The major cost of developing and adopting these rules other than staff time was the cost of publication which was \$ 2,239.44 for this publication and \$2,052.84 for the previous publication done in 2015 which was done for the telemedicine rule only.
6. A brief explanation of each rule and what prompted the rule is included at the end of this testimony.

7. A regulatory analysis was done regarding the telemedicine rule. The result of the regulatory analysis was that it was impossible to calculate the impact of this rule.
8. No small entity analysis was made as the board is exempt.
9. The rules have no fiscal effect.
10. No taking's assessment was required.
11. These rules were not adopted as emergency or interim rules.

Number 6: Brief description of each rule and the reason for enacting each rule.

50-02-02-01 Exceptions to technical requirements on licensure.

This rule was passed by the board after receiving applications from numerous applicants that were just slightly outside of the board's technical requirements to obtain licensure in the state of North Dakota. The board wanted to ensure the ability to license folks who are board-certified and would provide a unique or special contribution to the practice of medicine not readily available elsewhere within the state of North Dakota.

50-02-02.1 The Administrative License

This license was developed when reviewing applicants who had spent the majority of their time in administrative functions and wanted to continue to provide those services but hadn't practiced in some time. The license allows for the administrative function to continue but not allowing patient care. This license is one that has been utilized in other states as well.

50-01-15 Telemedicine

The telemedicine rule attempts to define the practice of telemedicine within the state ensuring that there is a standard of care that must be adhered to and defining how that standard of care is met. The board has been contemplating the rule on telemedicine since prior to 2015. In 2015 the Board approved this draft to move forward through the rule making process. The Board did hold a public meeting and hearing on this rule in 2015 and that process was not approved by the Attorney General's office for lack of proper notice.

The rule has not changed outside of minor corrections in numbering and grammar since it was noticed and reviewed in 2015. The summary of the comments received in 2015 as well as the summary of comments received in 2017 is attached for your review. Some of the comments remain the same and others are new.

In 2015 and in 2017 Teledoc requested less technology specific language seeking the use of a phone call with store and forward technology. The board has received and reviewed these comments twice now and remains dedicated to the current language which requires a like in-person meeting when establishing the licensee-patient relationship. There are a few reasons

that have been discussed by the Board to keep this language. The intent of the Board is to ensure that the standard of care is no different in an in person meeting with your provider than it would be through a telemedicine meeting. If the standard of care would require the provider to look into the patient's ear with an otoscope then that would be expected to be conducted through a telemedicine visit as well using technology and peripherals as necessary. The language in the rule allows for the provider to use their discretion in how to conduct future meetings with an established patient specifically, to allow proper follow up care. Again, the overall intent is to ensure that the standard of care is met for each patient interaction.

Another important issue the Board considered is the responsible stewardship of antibiotics. This discussion has not gone away since the original inception of creating this rule it has only become more emergent. I have also included a Power Point on this subject from Dr. Paul Carson within your materials.

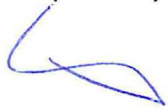
One of the comments that was received by the North Dakota Psychiatric Society was a new comment that was not made in 2015. This comment had to do with our prohibition of opioid prescribing through a telemedicine encounter. The Psychiatric Society has asked that an exception be made for medications used in Medication Assisted Treatment (MAT) such as buprenorphine. Although there was some support for this on the Board it was the decision of the Board not to create this exception. The medication referred to although it can treat opioid addiction it also has the potential to be abused, misused and diverted.

50-05-02 Prescription Drug Monitoring Program

This rule requires every practitioner with a DEA registration number to register with the prescription drug monitoring program and further defines how the prescription drug monitoring program should be utilized within their practice. This rule was based on action taken by the legislature in 2015. HB 1149 introduced by Representative Kaiser required all regulatory boards to require licensed individuals under the boards jurisdiction who prescribe or dispense controlled substances to utilize the prescription drug monitoring program.

I would be glad to try to answer any questions of the committee.

Respectfully submitted,



Bonnie Storbakken
Executive Secretary
North Dakota Board of Medicine

REGULATORY ANALYSIS

Proposed rule chapter 50-02-15, Telemedicine

The North Dakota Board of Medicine has proposed five administrative rules for hearing on September 26, 2017: one dealing with telemedicine, one dealing with administrative licenses, one dealing with special licenses, one dealing with the Physician Drug Monitoring Program (PDMP) and one dealing with the supervising physician for physician assistants. Only the proposed rule dealing with telemedicine requires a regulatory analysis.

The proposed telemedicine rule may have an impact on the regulated community in excess of fifty thousand dollars, although, for the reasons stated, it is not possible to quantify the amount of impact.

1. **Affected classes.** Physicians and physician assistants who wish to practice telemedicine will be affected by the proposed rule. There are no direct costs associated with the rule.

2. **Impact of the rule.** The rule permits the establishment of a patient-physician relationship through acceptable encounters and evaluations that occur with the patient in one location and the practitioner in another. It allows diagnoses and subsequent treatments, with the exception of prescribing opioids for pain management, based on such a telemedicine encounter. This will have a large impact on the regulated community with respect to how they may choose to deliver medical services. It will have a large impact on North Dakota citizens in terms of how they choose to obtain medical care.

The rule specifically excludes the establishment of a patient-physician relationship made only over the telephone or through a static online questionnaire as acceptable forms of telemedicine.

It is not possible to determine the positive economic impact for North Dakota licensed physicians -- who may or may not physically reside in North Dakota -- who diagnose and treat patients using approved telemedicine. Nor is it possible to determine the negative economic impact for those North Dakota licensed physicians working for a telemedicine company that chooses to utilize a method of telemedicine that is not acceptable under the rule, that is, telephone or online questionnaire only.

3. **Quantification of data.** It is not practicable to attempt to quantify the impact of the rule. It is dependent on an unknown number of encounters between North Dakota licensed physicians, over half of whom physically practice out of state, and North Dakota citizens. The field of telemedicine is changing rapidly, from more traditional forms, such as remotely reading radiology films, to direct-to-consumer primary care. The nature and costs associated with this type of care cannot be accurately predicted.

4. **Costs and revenues.** There will be a cost of approximately \$2,200.00 to implement the rule, primarily for publication costs. There are no other implementation costs. Nor are there identifiable enforcement costs.

5. **Consideration of alternate methods of regulating telemedicine.** The Board studied this issue for over a year and considered key alternatives to this rule. It published proposed policies on its website and requested comments from all licensees and the public regarding the appropriate regulation of telemedicine. It received numerous comments which informed the content of this rule. A list of those submitting comments, as well as the comments themselves, are available.

The board seriously considered many alternatives to the proposed rule, including the requirement of having an intervening health care provider at the site of patient during a remote encounter; regulating the technology required for acceptable telemedicine encounters; prohibiting the prescribing of all controlled substances through a telemedicine encounter; requiring the automatic provision of medical records to telemedicine patients; allowing telephone-only encounters or encounters based only on online questionnaires; allowing video encounters without the use of diagnostic tests or peripherals to be acceptable.

In the end, the board decided to impose a rule stating telemedicine rules must be the equivalent of an in-person evaluation or examination, and use the lab tests and peripheral tools that would be used in an in-person encounter. Diagnosis and treatment could then be done in the practitioner's discretion. It was felt this allowed the benefits of telemedicine to be enjoyed by North Dakota citizens while maintaining a standard of care equivalent to that required of more traditional medical encounters. The one exception was the prohibition of prescribing opioids for pain control through telemedicine, which was done to avoid exacerbating the prescription drug diversion and abuse epidemic currently facing the state and country.

Summary of oral comments received at the public hearing for proposed rules of the North Dakota Board of Medicine

The public meeting was opened at 9:00 am by Bonnie Storbakken the executive Secretary for the North Dakota Board of Medicine. Nine people attended the hearing, they are listed as follows:

1. Dr. Jason Tibbles representing Teledoc
2. Claudia Tucker representing Teledoc
3. John Ward from Zueger Kermis and Smith representing Teledoc
4. Marnie Walth representing Sanford Health
5. Dr. Chris Meeker representing Sanford Health
6. Dr. Andy McLean representing North Dakota Department of Human Services and UND SM HS
7. Courtney Koeble representing the North Dakota Medical Association
8. Megan Houn representing Blue Cross and Blue Shield of North Dakota
9. Luis San Jose representing himself.

Telemedicine Rule Comments:

1. The comments received from Dr. Andy McLean were regarding the prescribing section of the telemedicine rule. Dr. McLean states that the section regarding the prescription of opioids may have impact on treatment of opioid use disorders. As such, Dr. McLean suggested an exception to this section for prescribing done for medical assisted treatment. Dr. McLean also provided a written comment reiterating his analysis of the rule.
2. The comments received from the Teledoc representatives stated that they also provided a written comment in the form of a letter but wanted to appear in person to listen and participate in the hearing. The comments from Teledoc were related to the requirement of the use of audio visual in the development of a patient-licensee relationship. They stated that taking care of patients without video is done every day and that patients should have a choice in how they engage in their medical care. They suggested that the use of the standard of care language and less technology specific language would be better as innovation will always outrun technology. Removing the technology specific language would provide for more access as not all folks in North Dakota are in a place that has broad band internet.
3. The representatives from Sanford also centered on the development of the licensee-patient relationship. They stated that this relationship should be established by at least one face to face meeting or an initial video visit. This may allow the physician to uncover more of what is happening with the patient. There is a potential for misdiagnosis due to a lack of information.

No other comments were received at the hearing.

Summary of Written Comments received on the 2017 Rules Package.
2017

Telemedicine Rule:

Teledoc seeking changes regarding the requirement of a like in person examination specifically, the video requirement.

Sanford Health comments involve changing the language regarding the development of a valid patient relationship. There was support for a like in person examination from Sanford. Specifically, they used two way video or in person examination to establish the patient relationship within their recommended language.

Allergy and Asthma Network objected to the requirement of the use of audio visual technology to establish a patient licensee relationship.

New Benefits who asked for technology neutral language eliminating the requirement for audio visual technology to establish the physician patient relationship.

United Spinal Association who asked for elimination of the requirement of the use of video in establishing the physician patient relationship.

Dr. Andrew McLean seeking an exception for prescribing of buprenorphine products when used for MAT purposes.

North Dakota Psychiatric Society whose comments were seeking an exemption for prescriptions of medication used for medication assisted treatment (MAT).

Dr. Laura Lizakowski objecting to the prohibition of prescription of opiates via telemedicine based on her practice of palliative medicine and management of pain patients with metastatic cancers.

PDMP Comments

Sanford Health seeking to eliminate language from section 3 of the PDMP rule specifically the list of signs that would require the provider to check the PDMP and allowing for more general language to precipitate the requirement for checking the PDMP.

Attorney General

Seeking to add additional items to the list of signs requiring a practitioner to check at the PDMP based on the fact that they would be things readily noticeable by the physician.

Paul Azure

Objecting to the requirement to report prescriptions to the PDMP based on health care cost.



September 20, 2017

Bonnie Storbakken
Executive Secretary
North Dakota Board of Medicine
418 East Broadway, Suite 12
Bismarck, ND 58501

Re: Proposed Rules Relating to Telemedicine Services

Dear Ms. Storbakken:

Teladoc appreciates this opportunity to comment on the North Dakota Board of Medicine proposed rules relating to Telemedicine Services. Telemedicine is dynamic and evolving. Teladoc respects the role of the Board in considering the appropriate rules and clinical practice guidelines that are designed to be protective of public health and maintain high-quality care for patients while permissive of new technological innovations.

Teladoc is the nation's first and largest telehealth platform, delivering on-demand healthcare anytime, anywhere, via mobile devices, a web-based portal, video and interactive audio. We connect our enrollees with our network of more than 3100 board-certified physicians and mental health providers with an average of 15 years of physician experience. These physicians treat a wide range of conditions such as upper respiratory infection, urinary tract infection, influenza and sinusitis. Over 20.1 million enrollees now benefit from access to Teladoc 24 hours a day, seven days a week, 365 days a year. After more than a decade of service and over 2.5 million telehealth visits, Teladoc has yet to be subject to a single malpractice claim. With over 100 proprietary clinical guidelines, NCQA certification and our recent HITRUST certification, nothing is more important to Teladoc than quality health care.

Teladoc telehealth delivery model

Teladoc provides telemedicine services via web-based interactive audio-video visits or interactive audio using asynchronous store and forward technology, as selected by the patient. Teladoc physicians only treat minor, non-emergent, non-recurring medical issues with short-term prescriptions of common medications as may be appropriate to the diagnosis and standard of care. Teladoc physicians, where appropriate, advise the patient regarding whether that patient should seek an in-person consultation with a physician or go to an emergency room. The Teladoc physician may also refer the patient back to his or her primary care physician when appropriate.

Teladoc's services are only provided to patients through their employer, health-insurance company, state Medicaid plan or hospital system and are not open to the direct-to-consumer market. Only patients who have been appropriately validated through the Teladoc system may make appointments for a telehealth visit with Teladoc physicians.

Prior to a telehealth visit, the patient is required to complete a thorough medical history, including an overview of his or her care, allergies, medications, lab tests, family history, and the name of the



patient's primary care physician if he/she has one. The patient is then placed in the queue to receive a telehealth visit. There is less than 10 minutes median physician response time. A Teladoc physician licensed in the state where the patient is located must access the patient's medical history/electronic health record and review it prior to being given the patient's contact information to initiate the telehealth visit. The physician verifies the patient's identity, makes appropriate documentation in the patient's medical record, acquires the patient consent to diagnose and treat, establishes a diagnosis, and recommends treatment (where appropriate), all in accordance with the appropriate standard of care.

During a telehealth visit, an array of medical technology is available to appropriately address the patient's concerns. This includes the ability to have a secure videoconference as well as upload medical images and files in real time. The Teladoc electronic platform also allows for easy follow-up contact by the patient or physician at any point, and Teladoc physicians are authorized with patient consent to communicate with the patient's primary care physician whenever necessary or appropriate to ensure continuity of care. The patient's electronic health record ("EHR") is updated after each consultation, is easily accessible to the patient on an ongoing basis, and will be provided to the patient's physicians (including the primary care physician) with the patient's permission.

Significantly, Teladoc physicians do not prescribe DEA-controlled substances, non-therapeutic drugs, lifestyle drugs and certain other drugs which may be harmful because of their potential for abuse.

For emergencies, patients are told to immediately visit their local emergency room, call 911 or our physicians will make the call for the patient.

North Dakota Board of Medicine proposed rule 50-02-15

Teladoc applauds the Board's recognition that telemedicine is a valuable tool that uses technology and innovation to improve access to quality healthcare to the citizens of North Dakota. As the Board contemplates good public policy that removes barriers to access, it is important to note that the standard of care should be the same for telemedicine as it is for traditional in-person medicine. Physicians should use their professional judgement as to whether a telemedicine visit is appropriate and what technology is needed in order to establish a valid physician-patient relationship. Using the standard of care requirement, it is important that the Board use "technology neutral" language. As we know, technology advances are much faster than either the legislative or regulatory processes. As noted in HB 1038 which passed in the 2015 legislature, coverage for telehealth services included such technology neutral language; I cite that portion of the bill below:

g. "Telehealth":

(1) Means the use of interactive audio, video, or other telecommunications technology that is used by a health care provider or health care facility at a distant site to deliver health services at an originating site; and that is delivered over a secure connection that complies with the requirements of state and federal laws.



Accordingly, we submit the following recommendations to 50-02-05-03 that track with best practices on telemedicine policy throughout the country:

c) Evaluations and examinations required to establish a patient-license relationship. Prior to initially diagnosing or treating a patient for a specific illness or condition, an examination or evaluation must be performed. An examination or evaluation may be performed entirely through telemedicine, if the examination or evaluation is equivalent to an in-person examination. A video examination that utilizes appropriate diagnostic testing and use of peripherals that would be deemed necessary in a like in-person examination or evaluation would meet this standard, the use of interactive audio with asynchronous store and forward technology or audio-video, at the professional discretion of the physician, would meet this standard as would an examination conducted with an appropriately licensed intervening health care provider, practicing within the scope of their profession, providing necessary physical findings to the licensee. An examination or evaluation that consists only of a static online questionnaire or an audio conversation "in isolation" will not be considered to meet the standard of care.

We believe that the citizens of North Dakota should not be disenfranchised from access to affordable, quality healthcare just because they do not have access to broadband internet (needed for audio-video) or do not have a smartphone/computer or who do not have the capability to navigate through a web-based platform. We believe that the best technology should be made available to the patient, but the patient should have the right to choose how he/she accesses the telehealth visit with the physician's discretion.

Nationally, 62 million Americans do not have a primary care provider and we expect a 131,000 physician shortage by 2025. Eighty percent of ER visits are due to a lack of access to primary care. Telemedicine is a tool that will address the access to care issue, along with providing the citizens and businesses of North Dakota a way to decrease their costs for a doctor's visit to treat a simple non-emergent illness.

Thank you again for this opportunity to comment and for your kind consideration.

Sincerely,

Claudia Duck Tucker
Vice President, Government Affairs
Teladoc

cc: Dr. Jason Tibbels, Senior Medical Director, Teladoc
Adam Vandervoort, Chief Legal Officer, Teladoc

Lynette McDonald

Subject: FW: Rule Comments

From: McLean, Andrew J. [mailto:ajmclean@nd.gov]
Sent: Wednesday, September 27, 2017 10:50 AM
To: Lynette McDonald <LMcDonald@ndbom.org>
Subject: Re: Rule Comments

Hey, Lynette,
Here were my comments to the ND telehealth workgroup. If you need something more formal from me, let me know.
Andy
p.s. at end of week, work e-mail address: andrew.mclean@med.und.edu

50-02-15-04. Prescribing. A licensee who has performed a telemedicine examination or evaluation meeting the requirements of this chapter may prescribe medications according to the licensee's professional discretion and judgment, with one exception: Licensees may not prescribe opioids through a telemedicine encounter.

"Issue: This is more restrictive than Federal rules, in that controlled substances may be prescribed via telemedicine by a physician or physician assistant if an in-person evaluation of the patient has been performed by that provider. While caution needs to be taken in the prescribing of controlled substances, limiting an entire class of medication may place an undue burden on individuals, particularly those in rural areas who require medication assisted treatment (MAT) for opioid use disorders.

The recommendation would be to allow telemedicine prescribing of buprenorphine products when used for MAT purposes."

Sent from my iPhone

On Sep 27, 2017, at 10:06 AM, Lynette McDonald <LMcDonald@ndbom.org> wrote:

<p>CAUTION: This email originated from an outside source. Do not click links or open attachments unless you know they are safe.</p>
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DELIVERED VIA EMAIL

October 9, 2017

Ms. Bonnie Storbakken
Executive Secretary
North Dakota Board of Medicine
418 E Broadway Ave, Suite 12
Bismarck, ND 58501

RE: North Dakota Board of Medicine Notice of Intent, dated August 24, 2017, TO ENACT ADMINISTRATIVE RULES RELATING TO THE PRACTICE OF TELEMEDICINE AND TO THE ISSUANCE OF ADMINISTRATIVE MEDICAL LICENSES, AND TO ENACT ADMINISTRATIVE RULES RELATING TO PDMP REPORTING REQUIREMENTS, AND TO AMEND AN ADMINISTRATIVE RULE RELATING TO SPECIAL MEDICAL LICENSES, AND TO AMEND ADMINISTRATIVE RULES RELATING TO THE SUPERVISING PHYSICIAN FOR PHYSICIAN ASSISTANTS.

Dear Ms. Storbakken:

Sanford Health respectfully submits this comment in response to the above-referenced notice. We appreciate the opportunity to offer our perspectives on these proposed changes and outline how they might impact the patients we serve across North Dakota. These comments may be supplemented or amended as we gain further understanding of the issues.

1. Enactment of 50-02-15-01, NDAC, relating to the practice of telemedicine

As communicated to your predecessor, Mr. Houdek, Sanford shares the board's concerns for quality preservation as telemedicine becomes increasingly prominent in the delivery of care. It is Sanford's position that the proposed rule provide adequate flexibility to accommodate emerging technology-based care delivery systems and the capable medical judgment of this board's licensees. Accordingly, Sanford urges modifications to the proposed rule that:

- Define a "valid patient relationship" as one established through meaningful in-person or two-way video engagement;

- Give greater weight to the medical judgment of providers and the ethical standards to which they are held; and
- Within the context of a valid patient relationship, allow providers the professional latitude to deploy a full range of technological resources in a manner that still satisfies applicable medical standards of care.

Attached for your consideration as *Appendix I* is a redlined version of the proposed rule intended to capture the themes described above.

2. Enactment of 50-02-02.1, NDAC, relating to the issuance of administrative medical licenses

At this time, Sanford does not wish to offer comments on this rule.

3. Amendment to 50-02-02-01, NDAC, relating to special license requirements

At this time, Sanford does not wish to offer comments on this rule.

4. Enactment of 50-05-02, NDAC, relating to the PDMP

Sanford fully supports the promulgation of rules to thoughtfully address the serious issue of opioid abuse in North Dakota. Such efforts are consistent with Sanford's own proactive policies and educational initiatives, which continue to yield encouraging results.

As a dedicated partner in this effort, Sanford urges consideration of the following modifications intended to produce a stronger, clearer, more practical rule:

- Strike and add language to Section 2. A. as follows:

When a practitioner determines that reported drugs will be prescribed to a patient for a period to exceed 12 weeks, the practitioner, or his or her designee, shall request a PDMP report for that patient ~~and, at minimum, at least semi-annually thereafter.~~

The purpose of the above change is to promote efficient delegation of PDMP access and to create a simpler, cleaner requirement for PDMP consultation. Elimination of the latter

provision creates a clear instruction of PDMP access upon every prescription of reported drugs that exceeds 12 weeks.

- Strike and add language to Section 3 as follows:

In addition to those reports requested under paragraph 2, practitioners shall request a PDMP report when it is documented in the prescribing practitioner's medical record for that patient that the patient exhibits signs associated with diversion or abuse, including, but not limited to: prescribing reported drugs shall request a PDMP report when, upon examination of a patient, it is clinically apparent the patient is susceptible to diversion or abuse, or the prescribing practitioner's medical record for that patient reflects a readily discernible pattern of behavior suggesting the same.

- A. ~~Selling prescription drugs;~~*
- B. ~~Forging or altering a prescription;~~*
- C. ~~Stealing or borrowing reported drugs;~~*
- D. ~~Taking more than the prescribed dosage of any reported drug;~~*
- E. ~~Having a drug screen that indicates the presence of additional or illicit drugs;~~*
- F. ~~Being arrested, convicted or diverted by the criminal justice system for a drug-related offense;~~*
- G. ~~Receiving reported drugs from providers not reported to the treating practitioner; and~~*
- H. ~~Having a law enforcement or health professional express concern about the patient's use of drugs.~~*

The purpose of the above change is to more generally summarize the circumstances under which a practitioner should consult the PDMP, whether compelled by clinical observation or information discerned from a patient's medical record. This change places greater weight on a practitioner's medical judgment while still contemplating a wide range of factors. The laundry list of factors contained in the draft rule are not entirely applicable to or practically accessible within a patient's medical record.

- Strike Section 4.

The purpose of the above change is to promote clinical efficiency. It is Sanford's understanding that the PDMP system itself logs practitioner usage and could be consulted in

the event of a licensee investigation. Should the board see it appropriate to preserve this provision, Sanford recommends adding "or his or her designee" after the word "practitioner" for the same reasons stated under Section 2.A.

5. Amendment to 50-03-01-03, NDAC, relating to the supervision contract requirements for physician assistants

At this time, Sanford does not wish to offer comments on this rule.

6. Amendment to 54-03-01-05, NDAC, relating to the designation of a substitute primary supervising physician

At this time, Sanford does not wish to offer comments on this rule.

Thank you for the opportunity to offer comments. Sanford looks forward to working with you and the board to find the properly balanced approach to these important issues.

Sincerely,



Tim Rave,
Executive Director, Public Policy

APPENDIX I

CHAPTER 50-02-15 TELEMEDICINE

50-02-15-01. Definitions. As used in this chapter,

“Telemedicine” means the practice of medicine using electronic communication, information technologies or other means between a licensee in one location and a patient in another location, with or without an intervening healthcare provider. It includes direct interactive patient encounters as well as asynchronous store-and-forward technologies and remote monitoring.

“Licensee” means a physician or physician assistant licensed to practice in North Dakota. A physician assistant practicing telemedicine from another state is subject to the rules regarding physician supervision, except that supervision may be by a North Dakota licensed physician who is practicing telemedicine in North Dakota from the same state as the physician assistant, and need not be by a North Dakota licensed physician who is physically located in North Dakota.

“Valid patient relationship” means a relationship between a patient and licensee that is established through an initial in-person or two-way video examination or evaluation. For purposes of this chapter, a valid patient relationship created between a patient and licensee extends to all licensees of the same practice group or call coverage group.

50-02-05-02. Licensure. The practice of medicine is deemed to occur in the state the patient is located. Practitioners providing medical care to patients located in North Dakota are subject to the licensing and disciplinary laws of North Dakota and must possess an active North Dakota license for their profession.

50-02-05-03. Standard of care and professional ethics. Licensees are held to the same standard of care and same ethical standards whether practicing traditional, in-person, medicine or telemedicine. Therefore, the following apply in the context of telemedicine:

a) Scope of practice. Professional ethical standards require all practitioners to practice only in areas in which they have demonstrated competence, based on their training, ability and experience. In assessing a licensee’s compliance with this ethical requirement, consideration will be given to board certifications and specialty groups’ telemedicine standards.

b) Patient-Licensee relationship. A licensee practicing telemedicine must establish a valid patient relationship with the patient prior to the diagnosis and/or treatment of a patient. A licensee practicing telemedicine shall verify the identity of the patient seeking care; and disclose, and ensure the patient has the ability to verify, the identity and licensure status of any licensee providing medical services to the patient.

c) Evaluations and examinations required to establish a patient-licensee relationship. Prior to initially diagnosing or treating a patient for a specific illness or condition, an examination or evaluation must be performed. An examination or evaluation may be performed entirely through telemedicine, so long as the use of telemedicine permits the licensee to obtain necessary patient information to evaluate, diagnose and treat the patient in a manner consistent with applicable medical standards of care. ~~if the examination or evaluation is equivalent to an in-person examination. A video examination that utilizes appropriate diagnostic testing and use of~~

peripherals that would be deemed necessary in a like in-person examination or evaluation would meet this standard, as would an examination conducted with an appropriately licensed intervening health care provider, practicing within the scope of their profession, providing necessary physical findings to the licensee. An examination or evaluation that consists only of a static online questionnaire or an audio conversation will not be considered to meet the standard of care unless a valid patient relationship already exists.

Once a licensee conducts an acceptable examination or evaluation, whether in-person or by telemedicine, and establishes a patient-licensee-valid patient relationship, subsequent follow-up care may be provided as deemed appropriate by the licensee, or by a provider designated by the licensee to act temporarily in the licensee's absence.

It is recognized that in certain types of telemedicine utilizing asynchronous store-and-forward technology or electronic monitoring, such as tele-radiology or ICU monitoring, it is not medically necessary for an independent examination of the patient to be performed.

d) Medical records. Licensees practicing telemedicine are subject to all North Dakota laws governing the adequacy of medical records and the provision of medical records to the patient and other medical providers treating the patient.

e) Licensees must have the ability to make appropriate referrals of patients not amenable to diagnosis or complete treatment through a telemedicine encounter, including those patients in need of emergent care, or complementary in-person care.

50-02-15-04. Prescribing. A licensee who has performed a telemedicine examination or evaluation meeting the requirements of this chapter may prescribe medications according to the licensee's professional discretion and judgment, with one exception: Licensees may not prescribe opioids through a telemedicine encounter.

Licensees who prescribe controlled substances, as defined by North Dakota law, in circumstances allowed under this rule, must comply with all state and federal laws regarding the prescribing of controlled substances, and must participate in the North Dakota Prescription Drug Monitoring Program.

Lynette McDonald

From: Bonnie Storbakken
Sent: Friday, September 22, 2017 9:29 AM
To: Lynette McDonald
Subject: Fwd: proposed rule

Sent from my iPhone

Begin forwarded message:

From: LAURA LIZAKOWSKI <LLIZAKOWSKI@altru.org>
Date: September 22, 2017 at 9:03:21 AM CDT
To: "bstorbakken@ndbom.org" <bstorbakken@ndbom.org>
Subject: proposed rule

I am very concerned about the proposed rule to not allow providers to prescribe opiates via a telemedicine visit. I practice palliative medicine and manage pain of patients with metastatic cancers. Many of these patients are quite ill and weak and are in a lot of pain. Those long car rides can be quite difficult for them when they are having a lot of pain. It's really sad that we are now making blanket rules for all patients who are taking opiates. We've lost sight of compassion for who those patients who are suffering greatly and truly need those medications. I hope their voice is considered in all of this. Thank you.

Dr. Laura Lizakowski

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NORTH DAKOTA
PSYCHIATRIC
SOCIETY

A District Branch of the
American Psychiatric Association

October 9, 2017

Bonnie Storbakken
Executive Secretary
North Dakota Board of Medicine
418 E Broadway Ave, Suite 12
Bismarck, ND 58501

Dear Ms. Storbakken:

On behalf of the North Dakota Psychiatric Society, I would like to offer our support of the Board of Medicine's proposed telemedicine administrative rules, with one suggested change.

The rule as currently written would require an in-person visit for every prescription of medication used for Medication Assisted Treatment (MAT). Medication such as Buprenorphine is technically an opioid, and therefore, under the current draft of the rules, would require an in-person visit every time it is prescribed. This may act as a disincentive for follow up visits if every visit to obtain medication must be in person.

Telemedicine, a key innovation in support of health care delivery reform, is being used in initiatives to improve access to care, care coordination and quality, as well as reduce the rate of growth in health care spending. Patients in rural areas of North Dakota have to drive long distances to get to a treatment center or to see an addiction specialist for medication-assisted treatment. Telemedicine could reduce the burden of this barrier.

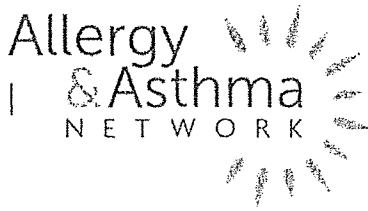
The North Dakota Psychiatric Society supports policies that carefully regulate the adoption of telemedicine, while still allowing physicians to more easily and readily connect to their patients and facilitate consultations through these technologies. The proposed rules, with the amendment with regard to MAT, would accomplish this.

Thank you for your leadership on this issue.

Sincerely,

Emmet Kenney, MD
President, ND Psychiatric Society

OCT 09 2017



8229 Boone Boulevard, Suite 260, Vienna VA 22182 • 800.878.4403 • AllergyAsthmaNetwork.org

October 9, 2017

North Dakota Board of Medicine
418 E. Broadway Avenue, Suite 12
Bismarck, North Dakota 58501

Re: Proposed rules pertaining to telemedicine

Dear Members of the North Dakota Board of Medicine:

Allergy & Asthma Network supports telemedicine legislation and regulations that maximize allowable technologies and enable patients to have greater access to high-quality care. As the leading national nonprofit dedicated to protecting and improving the health of people with asthma, allergies and related conditions, we believe progressive policies regarding telemedicine are essential to fulfilling that goal.

In its current form, proposed regulation 50-02-15 inhibits North Dakotans ability to utilize telemedicine services for affordable, convenient care by including a medically-unnecessary provision requiring the use of audio-visual technology to establish a patient-license relationship. A high-speed Internet connection is needed to support streaming video, and many North Dakotans lack access to such broadband Internet service.

Physicians who deliver care through telemedicine should be held to the same standards as they would be if they were treating a patient in an office. Many patients who suffer from allergies, especially those with allergy-related skin conditions, would benefit from greater and more convenient access to a physician. For patients with chronic respiratory conditions like asthma and COPD, telemedicine would be an effective way to provide disease education and improved disease management. This is particularly true in North Dakota's many rural areas, where visiting a physician's office could require traveling lengthy distances through adverse weather conditions.

We believe telemedicine functions as a complement to existing healthcare resources by increasing access to affordable medical treatment. Allergic reactions and related conditions can occur at any time, and patients should have the option to pursue treatment through telemedicine rather than traveling to a hospital's emergency room in the middle of the night.

We respectfully request that the Board remove the audio-visual mandate from the proposed regulation. Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink that reads "Tonya A. Winders". The signature is written in a cursive, flowing style.

Tonya Winders
President and CEO



October 6, 2017

VIA EMAIL

North Dakota Board of Medicine
418 E Broadway Ave, Suite 12
Bismarck, ND 58501

Dear Members of the Committee:

I am writing on behalf of New Benefits to request that the proposed telemedicine regulations (Rule 50-02-05-03) before you be amended to allow the patient-license relationship to be established via interactive audio as well as through video. We believe the state should create telemedicine policies that preserve consistent standards and allow physicians to use their knowledge and experience in deciding whether to use modern technology to provide care, without narrowly defining allowable technologies.

For more than a decade, we have offered telemedicine services through Teladoc to our members. Although New Benefits is headquartered in Texas, our presence in North Dakota is substantial. We work with clients such as MBI Energy Services, Cracker Barrel, and Red Lobster, as well as a number of small businesses and school systems. We connect North Dakota residents with North-Dakota licensed physicians, who provide affordable, high-quality treatment of common, non-emergency ailments, and we have received virtually no complaints. Our experience is telemedicine provides patients with high-quality care that is safe, secure, timely and cost-effective.

My hope is that the Board will incorporate technology neutral language into rule 50-02-05-03 which does not require audio-visual technology to establish the physician-patient relationship via telemedicine.

This one change will position North Dakota to take advantage of telemedicine to address the significant areas of the state currently medically underserved and provide employers with a much-needed tool to manage health care costs.

I would be pleased to answer any questions you may have about our experience with telemedicine and can be reached at 1-800-800-8304 x1615.

Sincerely,

A handwritten signature in black ink that reads "Joel Ray". The signature is written in a cursive, flowing style.

Joel Ray, CEO

October 13, 2017

North Dakota Board of Medicine
418 E Broadway Ave, Suite 12
Bismarck, ND 58501

Re: Chapter 50-02-15 and the use of telemedicine

Dear Members of the Board:

United Spinal Association writes to submit public comments requesting that the language in draft regulation Chapter 50-02-15 be amended. We understand the formal comment period has just passed, but we hope that our organization's views will be considered at the board meeting next week as you take up the issue of telemedicine. Specifically, amending the restrictive language carving out allowable technology in telemedicine will allow the state of North Dakota to maximize expanded access to healthcare for people with disabilities through telemedicine. United Spinal Association supports public policies to promote and improve the quality of life for individuals with spinal cord injuries and diseases.

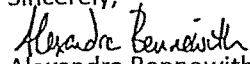
United Spinal Association is the largest disability-led national non-profit organization founded by paralyzed veterans in 1946 and has since provided service programs and advocacy to improve the quality of life of those across the life span living with spinal cord injuries and disorders (SCI/D) such as multiple sclerosis, amyotrophic lateral sclerosis (ALS), post-polio syndrome and spina bifida. United Spinal represents over one million individuals with spinal cord injuries and disorders, over 50 chapters, over 100 rehabilitation hospital members and close to 200 support groups nationwide. Throughout its history, United Spinal Association has devoted its energies, talents and programs to improving the quality of life for these Americans and for advancing their independence. United Spinal Association is also a VA-recognized veterans service organization (VSO) serving veterans with disabilities of all kinds.

United Spinal Association respectfully requests the Committee amend draft Chapter 50-02-15 to insert language in Section 3. Subsection (c) to explicitly allow the use of video in establishing the physician-patient relationship. The current requirement for audio-visual connections in establishing this relationship creates a barrier to access and removes another avenue for individuals with disabilities to obtain quality intervention via telemedicine.

Telemedicine is a valuable tool for meeting the needs of North Dakotans, particularly those with disabilities, and United Spinal Association strongly supports technology-neutral telemedicine regulations for the purpose of improving public access to high-quality health care. For people in rural areas and those living with spinal cord injuries or other physical disabilities, obtaining in-person care can be a difficult process.

While it is important that telemedicine providers be regulated to protect the public, it is equally important that policies not be designed to impede access. With the requested amendments, the state's telemedicine regulations would ensure that North Dakotans have greater access to medical care from providers that comply with federal and state requirements. If you have any questions, please do not hesitate to contact Jasey Cárdenas, Senior Policy Associate, at jcardenas@unitedspinal.org or (202) 556-2076, x7104.

Sincerely,



Alexandra Bennewith, MPA

Vice President, Government Relations

Lynette McDonald

From: Bonnie Storbakken
Sent: Friday, October 13, 2017 4:10 PM
To: Lynette McDonald
Subject: Fwd: United Spinal Association Comments on Chapter draft regulation 50-02-15
Attachments: image001.png; ATT00001.htm; United Spinal Association - ND Reg Chapter 50-02-15.pdf; ATT00002.htm

We may want to note that receipt of these was past our deadline but include anyway.

Sent from my iPhone

Begin forwarded message:

From: Jasey Cardenas <jcardenas@unitedspinal.org>
Date: October 13, 2017 at 3:17:36 PM CDT
To: "bstorbakken@ndbom.org" <bstorbakken@ndbom.org>
Cc: Alexandra Bennewith <ABennewith@unitedspinal.org>
Subject: United Spinal Association Comments on Chapter draft regulation 50-02-15

Hello,

United Spinal Association would like to submit our comments on draft regulation Chapter 50-02-15. We understand the formal comment period has just passed, but we hope that our organization's views will be considered at the board meeting next week as you take up the issue of telemedicine.

We are requesting that that the language in draft regulation Chapter 50-02-15 be amended. Specifically, amending the restrictive language carving out allowable technology in telemedicine will allow the state of North Dakota to maximize expanded access to healthcare for people with disabilities through telemedicine.

Please let me know if you have any questions. Have a great weekend!

About United Spinal Association:

United Spinal Association is the largest disability-led national non-profit organization founded by paralyzed veterans in 1946 and has since provided service programs and advocacy to improve the quality of life of those across the life span living with spinal cord injuries and disorders (SCI/D) such as multiple sclerosis, amyotrophic lateral sclerosis (ALS), post-polio syndrome and spina bifida. United Spinal has over 49,000 members and represents over one million individuals with spinal cord injuries and disorders, over 50 chapters, over 100 rehabilitation hospital members and close to 200 support groups nationwide. Throughout its history, United Spinal Association has devoted its energies, talents and programs to improving the quality of life for these Americans and for advancing their independence. United Spinal Association is also a VA-recognized veterans service organization (VSO) serving veterans with disabilities of all kinds.

Thank you,

Jasey Cárdenas, Senior Policy Associate
United Spinal Association

1660 L Street NW, Suite 504

Washington, DC 20036

Office: 202-556-2076 ext. 7104 Fax: 202-223-2380

E-mail: jcardenas@unitedspinal.org Web: www.unitedspinal.org

Lynette McDonald

From: Bonnie Storbakken
Sent: Monday, September 25, 2017 10:48 AM
To: Lynette McDonald
Subject: Fwd: Follow up from our discussion yesterday.

Not sure I sent this to you. This is the official comment of the Attorney General.

Sent from my iPhone

Begin forwarded message:

From: "Seibel, Troy T." <tseibel@nd.gov>
Date: September 22, 2017 at 10:33:53 AM CDT
To: Bonnie Storbakken <BStorbakken@ndbom.org>
Subject: RE: Follow up from our discussion yesterday.

Bonnie,

Yes, I think that accurately reflects what we discussed. Thanks.

Troy T. Seibel
Chief Deputy Attorney General
Office of Attorney General
600 E. Boulevard Ave., Dept. 125
Bismarck, ND 58505
701-328-2210
tseibel@nd.gov

From: Bonnie Storbakken [<mailto:BStorbakken@ndbom.org>]
Sent: Wednesday, September 20, 2017 2:34 PM
To: Seibel, Troy T. <tseibel@nd.gov>
Subject: Follow up from our discussion yesterday.

<p>CAUTION: This email originated from an outside source. Do not click links or open attachments unless you know they are safe.</p>
--

Hello Troy,

I wanted to clarify the official comments From the Attorney General regarding our PDMP rule before they are added to the comments for review by our board.

It is suggested that the Board consider adding the following language because they would be indicators that prescribers would notice and may be suggestive of an issue of one type or another regarding scheduled medications.

This language should be added to the list under section 3.

1. Violating any prescribing agreement with the physician;
2. Frequently requests early refills of a reported drug for any reason;
3. Appears impaired or excessively sedated to the physician in any patient encounter;
4. Has a history of drug abuse or dependency.

Does this accurately reflect the comments that were intended to be considered?

Thank you,
Bonnie

Bonnie Storbakken
Executive Secretary
North Dakota Board of Medicine
418 East Broadway Ave.
Bismarck, ND 58501

(701)328-6500

Bonnie Storbakken

From: info@ndbom.org
Sent: Tuesday, September 5, 2017 6:06 AM
To: Bonnie Storbakken
Subject: Contact Form Submission

Contact Form Submission: Please login to view at <https://www.ndbom.org/admin/cgi-bin/contactadmin.pl>.

www.ndbom.org/admin/cgi-bin/contactadmin.pl?action=display&contact_id=2798

Submitted values

Name = Paul Azure

Address = Wahpeton

City = Wahpeton

State = ND

Zip = 58075

Phone = 7014034898

Email = paulazure@hotmail.com

Comments = Trying to comment on the administration rules butt could not find the phone number that was supposed to be listed. Will make my comments here, if that is not acceptable call me. I question 50-05.02 reporting medication, and I ask that the full board review this rule and consider the effect this will have when the Congress eliminates federal health care. the cost of the uninsured to health care is going to have to come down or civil unrest and riots like you have never seen will start to happen. Perhaps this board should be eliminating rules and restrictions instead of making more. again I ask that the board consider the outcome of all of the proposed rules, with the effect they will have on the uninsured population that will have to pay cash for their health care

TELEMEDICINE RULE COMMENT

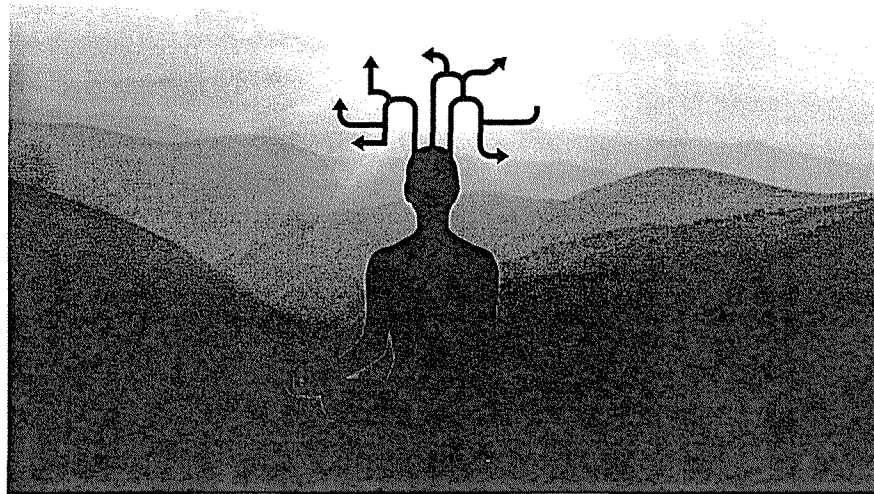
Attached are the rules comments we received following our public hearing on October 12th. The comment period ended October 23rd under law, but I've included all comments received, whether they arrived by that date or not.

Some, such as the ND Psychiatric Assn., ND Board of Pharmacy, Health Partners, Dr. Andy McLean, supported the rule as written.

There was a consistent theme for those suggesting changes and it dealt with follow-up care and on-call physicians within a group. Sometimes we get very close to an issue and, perhaps, what seemed pretty clear to me when drafting this rule may not have been clear to others. At any rate, I've drafted an additional paragraph to the rule that makes it clear that 1) follow up care, after a physician-patient relationship is established by the first examination or evaluation (in person or telemedicine), may be done in any way deemed appropriate by the physician or physician assistant. This would allow follow-up phone calls, emails, etc., which I know the board does not intend to prohibit; and 2) on call providers designated by a licensee would be covered by this, as well as the treating provider. I think this covers the objections listed by most of the commenters.

A suggestion by Teladoc, that we change the language and allow a phone call with asynchronous store and forward technology, is not clear to me, as I don't understand what that asynchronous store and forward material would be. Usually, that term is used to describe items such as radiology images, but I don't think that's what Teladoc means. They will be at the hearing, so perhaps we can get clarification on the point. Their language would greatly expand the use of just audio calls, as opposed to our standard language requiring a video component.

Antibiotic Mindfulness - Becoming Better Stewards of a Precious Resource



Paul J. Carson, MD, FACP



Dept. of Public Health,
Management of Infectious Diseases

What Is Stewardship?



Merriam-Webster:

“The careful and responsible management of something entrusted to one's care”

“The responsible overseeing and protection of something considered worth caring for and preserving”

Thanks to PENICILLIN
...He Will Come Home!



"Because infectious diseases have been largely controlled in the United States, we can now close the book on infectious diseases."

- William Stewart, MD
U.S. Surgeon General, 1967



"Don't forget to take a handful of our complimentary antibiotics on your way out."

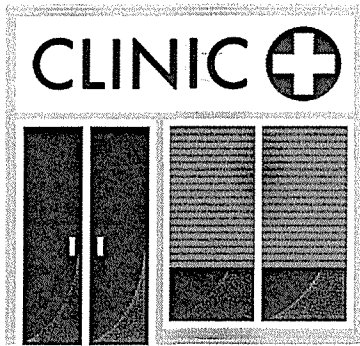
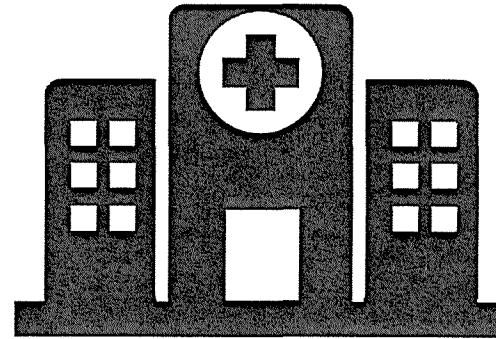
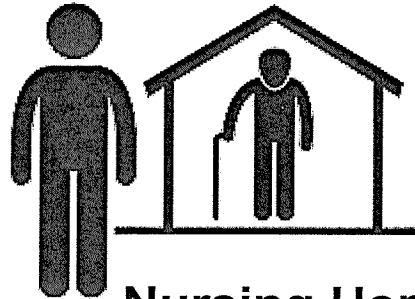
Conspicuous Consumption

- 5 out of every 6 Americans will receive a course of antibiotics annually
- 160-258 million antibiotic Rx ($\approx$ 3 million kg) / yr
- Avg American child will receive 10-20 courses of antibiotics before age 18
- Not atypical for a 2 y.o. to have spent $\approx$ 3 mos of their life on antibiotics



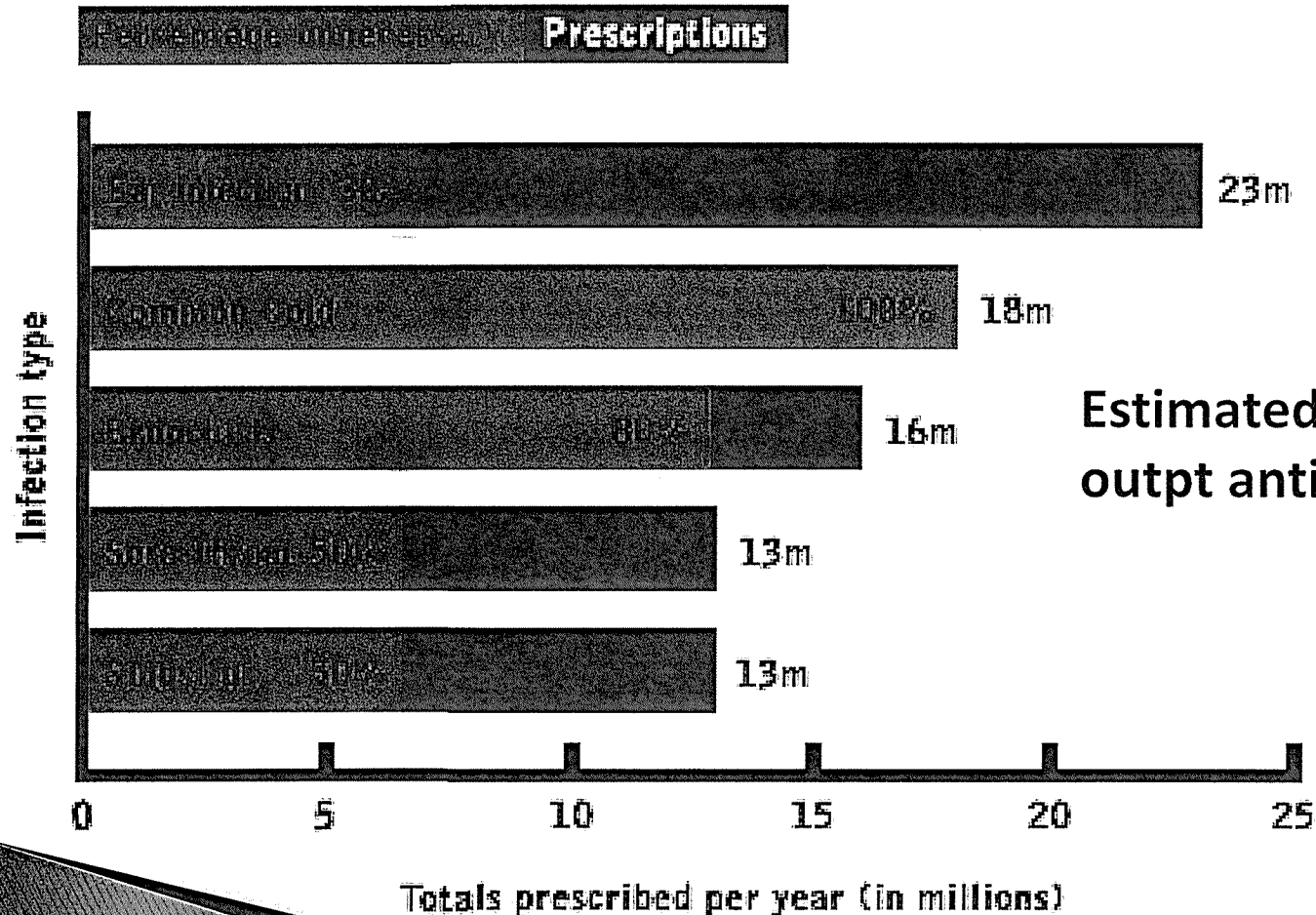
Wenzel RP and Edmond MB. *N Engl J Med.* 2000;343:1961-1963
Spellberg and Bartlett. *N Engl J Med.* 2013; 368:299-302
Hicks and Taylor. *N Engl J Med.* 2013; 368; 1461-1462

Antibiotics Across the Health Care Spectrum



Nursing Home

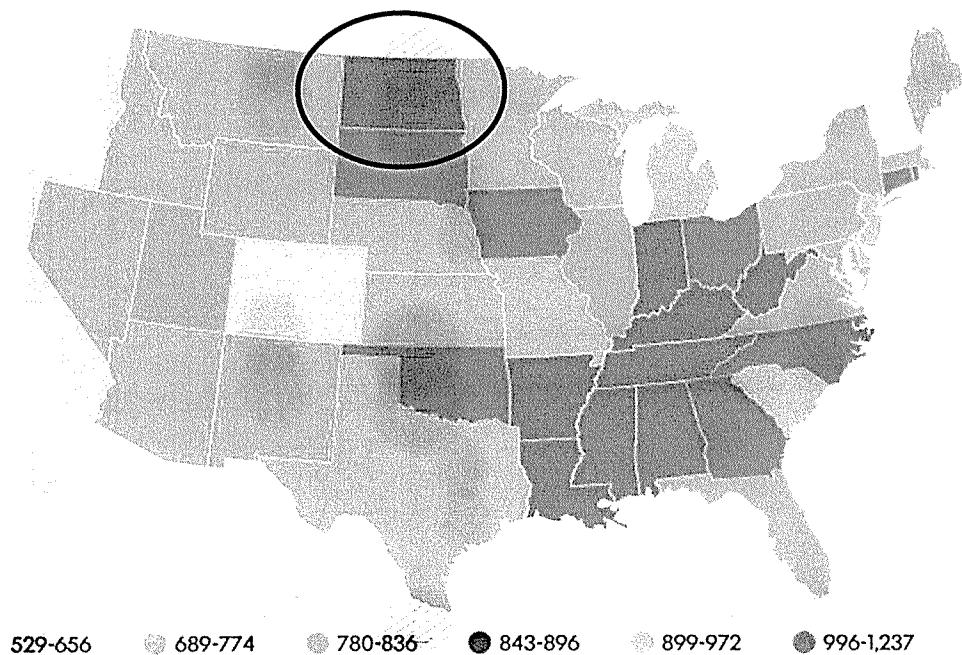
Unnecessary Antibiotic Prescriptions



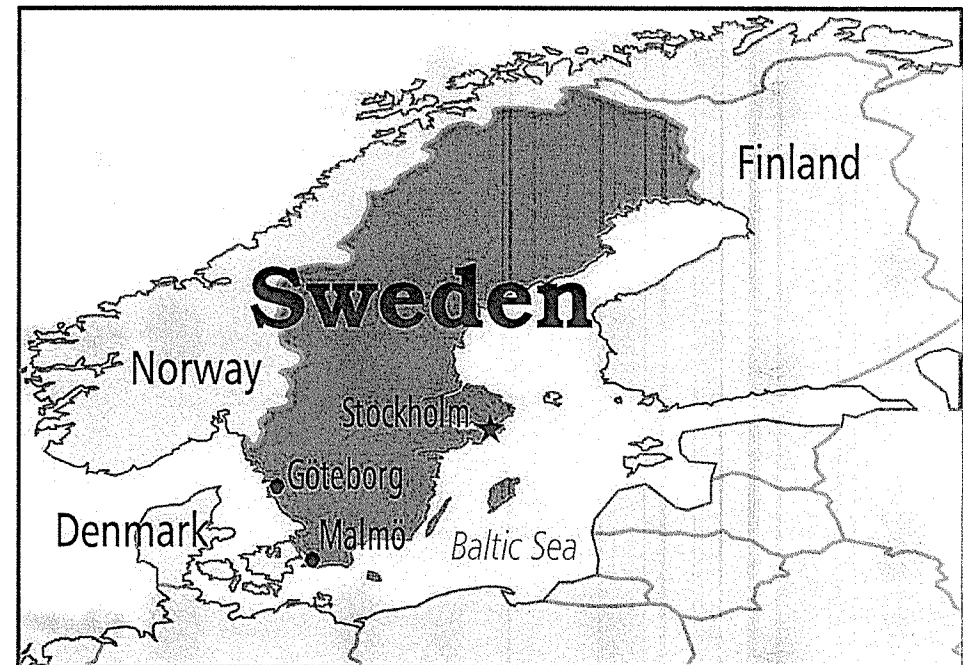
Estimated 50 million unnecessary outpatient antibiotic prescriptions / yr

CDC

A Tale of Two Countries: Rate of Outpatient Antibiotic Use, 2014



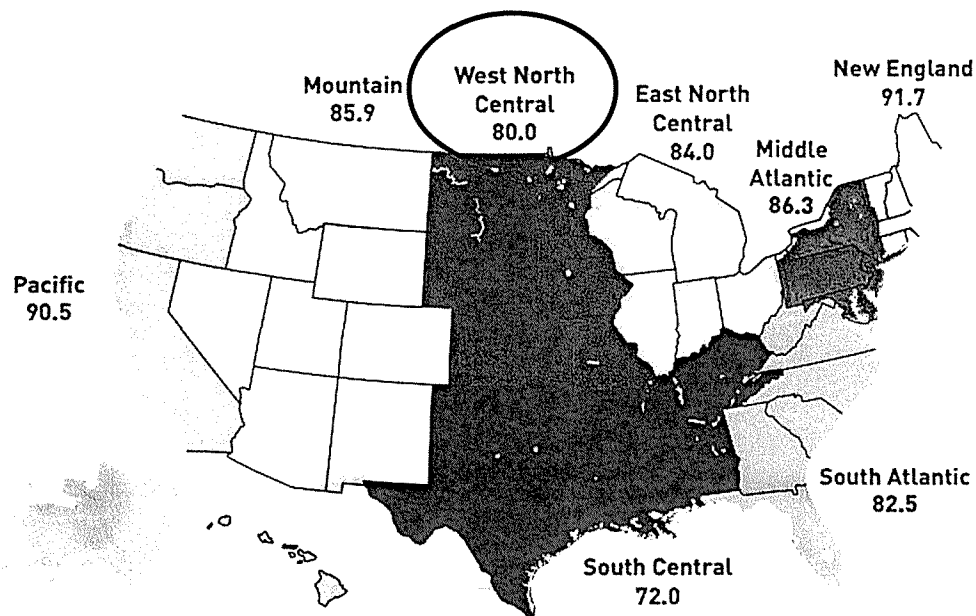
835 / 1000 population / yr



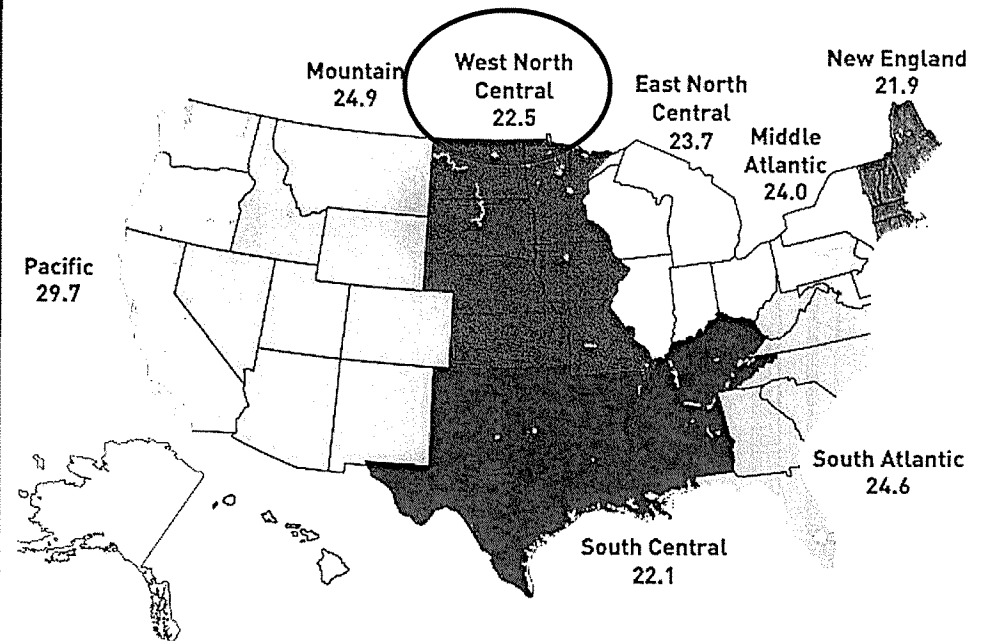
328 / 1000 population / yr

Geographic Variability in HEDIS Measures Related to Appropriate Antibiotic Use

Children diagnosed with VURI
not receiving an antibiotic, 2008-2012



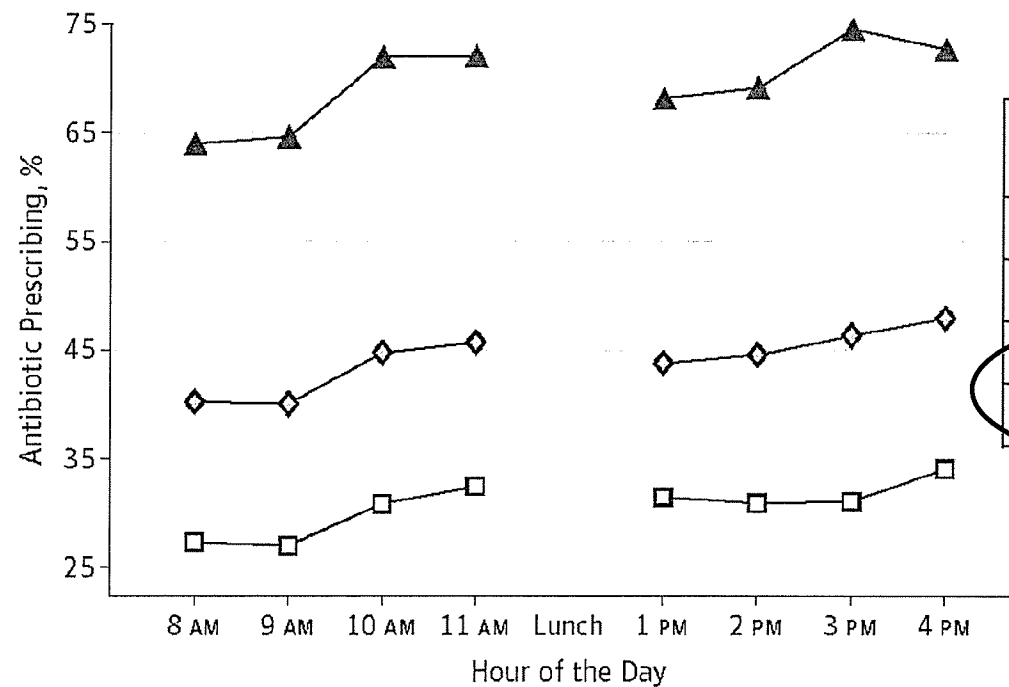
Adults with acute bronchitis
not receiving an antibiotic, 2008-2012



Antibiotic Prescribing Increases with Fatigue



▲ Antibiotics sometimes indicated (n = 7544)
 ◇ Overall (n = 21 867)
 □ Antibiotics never indicated (n = 14 323)

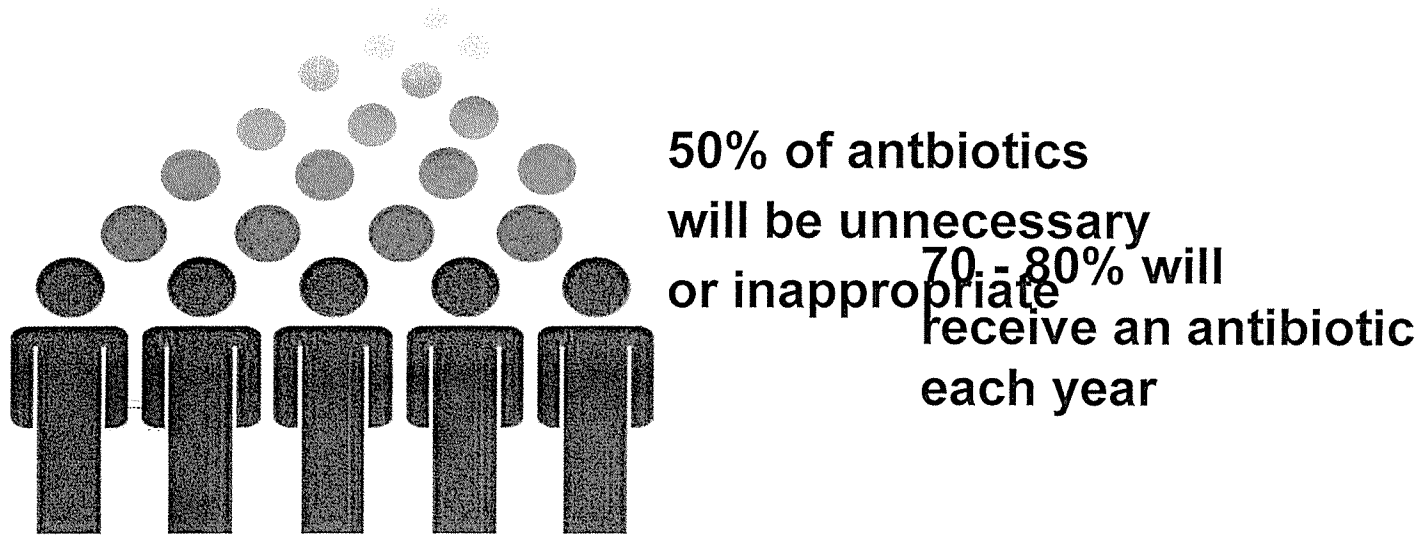


Clinic hour	RR
1	1.0
2	1.01 (0.91-1.13)
3	1.14 (1.02 - 1.27)
4	1.26 (1.13 - 1.41)

P < .001 for linear trend

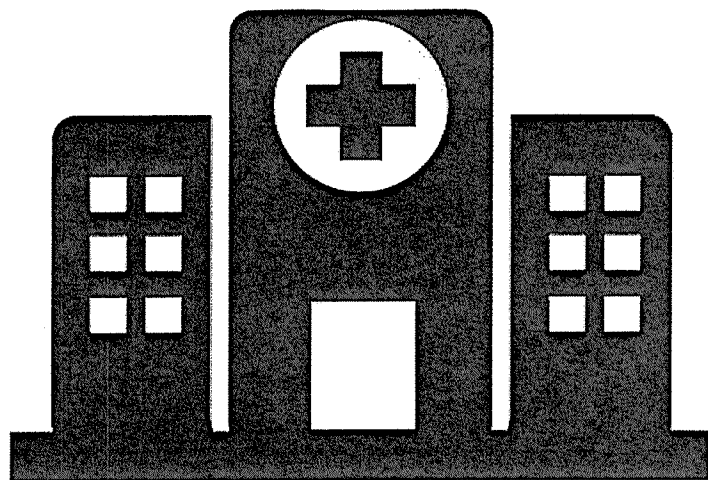
Linder JA et al. JAMA Intern Med 2014;174:2029-31.

Overuse of Antibiotics in Nursing Homes



- 2 million will receive unnecessary or inappropriate antibiotics

Trends in Hospital Antibiotic Use from 2002-2006



Vancomycin



43%

Carbapenems



59%

**Piperacillin-
Tazobactam**

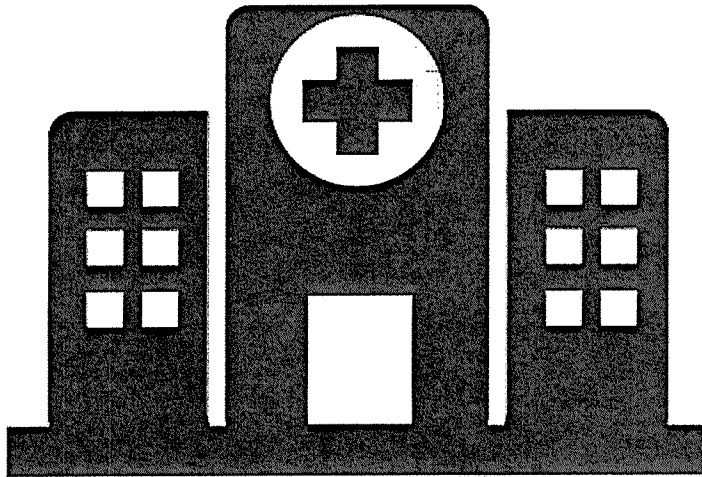


84%

Hecker MT, et al. *Arch Intern Med* 2003;163:972-978

Pakyz AL, et al. *Arch Intern Med.* 2008;168(20):2254-2260

Trends in Hospital Antibiotic Use from 2002-2006



**30 - 50% of Antibiotic Use
Unnecessary or Inappropriate**

Hecker MT, et al. *Arch Intern Med* 2003;163:972-978

Pakyz AL, et al. *Arch Intern Med.* 2008;168(20):2254-2260

BAD BUGS, NO DRUGS

As Antibiotic Discovery Stagnates ...
A Public Health Crisis Brews



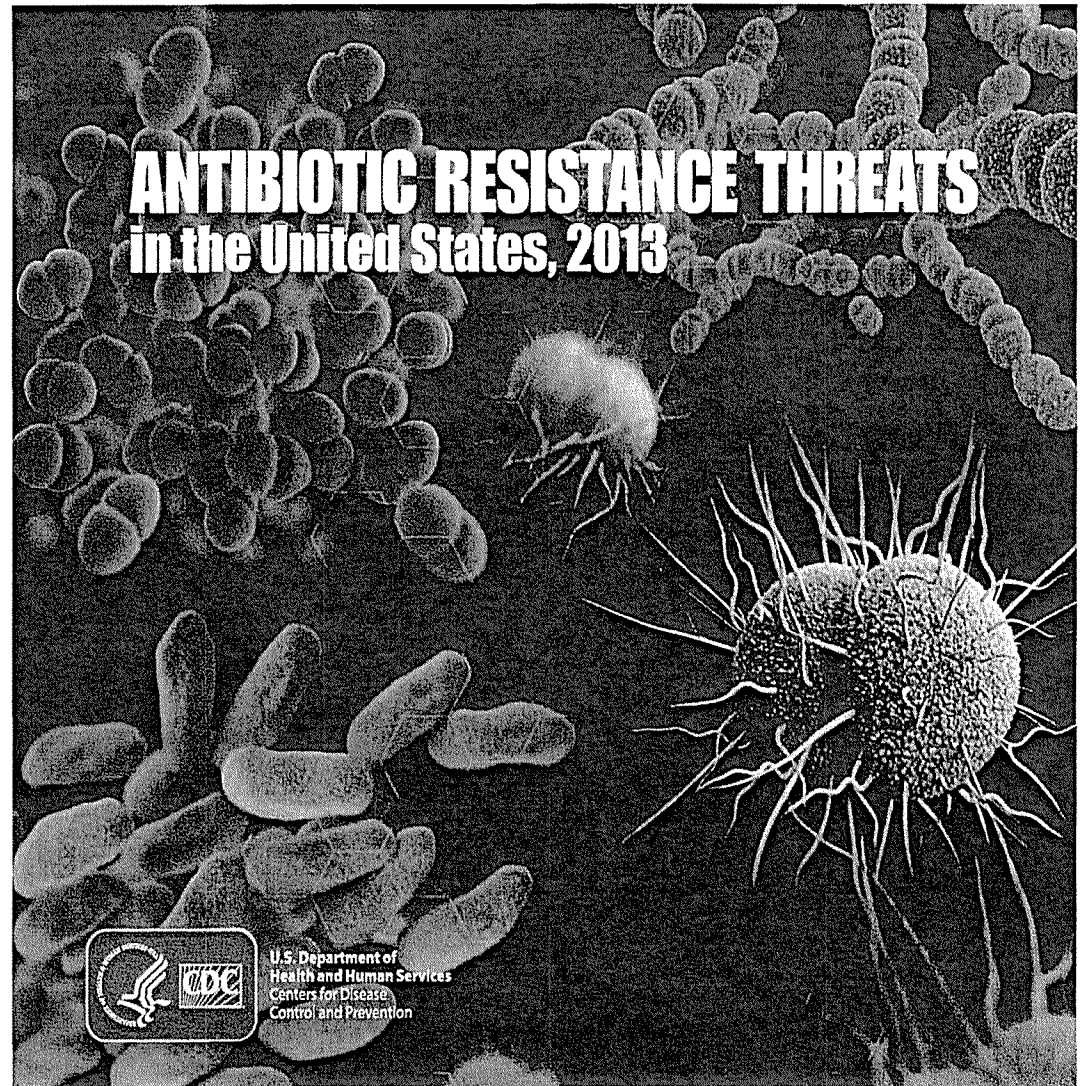
 **IDS**A
Infectious Diseases Society of America

July 2004

**Bad Bugs
Need Drugs**



April 2010



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

CDC Hazard Level for Antibiotic Resistance Threats - 2013

Concerning	Serious	Urgent
VRSA	MRSA	<i>Clostridium difficile</i> (C. diff)
Ery-R GABHS	VRE	Carbapenem-R Enterobacteriaceae
Clinda-R GBBHS	MDR-Pseudomonas	Drug-resistant <i>N. gonorrhoeae</i>
	ESBL-Enterobacteriaceae	
	DR-Campylobacter	
	DR-Salmonella	
	Fluconazole-R Candida sp	
	MDR-Acinetobacter	
	MDR/XDR TB	