

NC Communicable Disease Law

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SLIDE 1

Hello everyone. This is Jill Moore. I am a faculty member with the School of Government at UNC-Chapel Hill, and I work in the area of public health law. I'm happy to be available to you via this webinar, and I'm also happy to be of assistance to you at other times if you have questions or want to talk through a particular issue in North Carolina communicable disease law. The last slide that I'll have today has my contact information on it and you are most welcome to use it.

My topic is North Carolina communicable disease law. A lot of communicable disease law is state-specific and I'll be talking in a fair amount of detail about some laws that are specific to North Carolina. Please be aware that the same legal questions might be answered differently if you practice in another state.

SLIDE 2

Here are the learning objectives for this part of the program. By the end of the session, you should be able to:

- Locate NC communicable disease laws
- Identify laws giving public health officials access to records for investigations
- List sources of communicable disease control measures
- Describe options for enforcing communicable disease laws
- Describe NC's medical and religious exemptions to immunization requirements
- Explain informed consent for HIV testing under NC law

This is an ambitious set of objectives and I wouldn't expect everyone to have all aspects of today's presentation committed to memory by the end, but I do want you to at least be aware that we have law on all these issues, and I want you to be able to find it when you need it.

SLIDE 3

Let's start by talking about North Carolina communicable disease laws, where they come from and where to find them.

SLIDE 4

We tend to talk about “the law” as if it were some singular thing, but in fact there are many different sources of law in the United States and in North Carolina. I've listed three main sources here: statutes, rules, and court cases. Now I should be clear that those aren't the only sources of law there are. The constitution is a source of law. Contracts are a source of law for the people or agencies who are parties to the contract. But these three are the main ones that we deal with in practice, when public health activities to control communicable disease raise legal questions.

Statutes, rules, and court cases serve different purposes that are outlined here.

Statutes are the laws the legislature makes to enact particular policy choices. They are usually fairly general in nature – they'll provide the guiding principles for our public health actions by telling you what you're allowed to do or sometimes what you're prohibited from doing, but they usually don't get into nitty-gritty details. For example, a statute may require a child to be immunized, but it won't specify the immunizations. Rather, the statute will authorize some other entity to flesh out those details ...

Often by adopting **Rules**, another source of law. This is where you find many of the details of communicable disease laws, such as those immunizations I referred to, or the list of diseases which must be reported, or particular control measures. I'll have a lot more to say about rules later.

The third source of law I want to briefly mention now are **court cases**. Courts resolve legal issues that arise in particular cases or controversies. Cases are significant to us because they may result in new rules of law that we need to follow, or they may clarify the meaning of a statute or administrative rule, or tell us how to apply it.

All of these are “the law.”

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The North Carolina General Statutes are the laws adopted by our state legislature, the North Carolina General Assembly.

Statutes give us our general framework for communicable disease law but they don't give us all the specifics. Most of the specifics are in rules, which we'll talk about in a moment.

So what do our statutes do?

- We have laws that require physicians and certain others to report communicable diseases and conditions to public health.
- Another law requires people to comply with communicable disease control measures. The statute doesn't say what those control measures are, but it authorizes the Commission for Public Health to adopt rules establishing the control measures.
- We also have a law allowing either the state health director or a local health director to order isolation or quarantine. Part of that law provides what we call "due process" protections for people who are isolated or quarantined – what that means is that it gives people who are subject to the orders a way to have the orders reviewed by a court.
- And we also have statutes that address the confidentiality of communicable disease information, when and how you have to get informed consent—and when you don't—for some communicable disease tests or treatments, and methods for enforcing the communicable disease laws.

Let's jump back up to the second bullet point for some information about where to find North Carolina's communicable disease statutes. Most of the laws that are relevant to communicable disease law are in Chapter 130A of the North Carolina General Statutes. If you have access to a law library you can look them up in a book that looks like this, but if you don't have access to the books you can find them on line at the link you see here. This link goes to the North Carolina General Assembly's webpage, which has a link to the complete General Statutes.

I mentioned earlier that statutes set out general policy directions but they don't always get into the details. For example, we have a statute that says we're going to have required communicable disease control measures but it doesn't say what those are – instead, it says we'll have rules telling us what those are. Let's take a look now at rules.

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North Carolina's communicable disease rules are adopted by an entity called the North Carolina Commission for Public Health. The Commission has 13 members, 9 appointed by the Governor and 4 selected by the NC Medical Society. The membership is in similar to what you see on a

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local board of health, including physicians, a pharmacist, a nurse, a veterinarian, an engineer and so forth.

The Commission makes statewide rules that have the force of law, which is a pretty significant authority. However, the Commission is not allowed to adopt just any rule that it thinks might be a good idea – it can only adopt rules that the General Assembly has authorized it to adopt. I mentioned earlier that the statutes adopted by the General Assembly set the policy direction for the state but rules fill in the details, and the Commission’s role is limited to just that – figuring out the details of policy decisions the legislature has made.

The Commission has been specifically authorized to adopt communicable disease rules. There are actually several laws that provide this authority: one is written in general terms and authorizes rules for the detection, control and prevention of communicable diseases (GS 130A-147); another specifically authorizes the Commission to adopt control measures; yet another specifically authorizes the Commission to create the list of reportable communicable diseases. And the Commission has done all those things, as you see in the third bullet point here. The Commission also is specifically authorized to adopt rules setting out the childhood immunization schedule and addressing how immunization information may be shared, and it has done that.

I want to briefly mention a new law called the Regulatory Reform Act of 2013. We don’t need to talk about that in detail today, but be aware that one of the things it did was require state agencies to review all of their rules over the next few years and potentially make some changes. The communicable disease rules will have to be reviewed just like all the rest. The process of conducting these reviews is going to be time- and labor-intensive, but the Division of Public Health has set out a schedule for getting it done in accordance with the time frames in the regulatory reform act. The communicable disease rules review is scheduled to be complete by the end of 2017.

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Let’s talk now about case law, or the body of law that is made by judges. My retired colleague David Lawrence used to say that the meaning of a statute is not fixed until a court interprets it. That is true and the same could be said for rules. However, in North Carolina, we have a lot of communicable disease statutes and rules and very few court cases interpreting them, and it’s been like that for decades. We rely a lot on practice and policy guidance in interpreting our rules and statutes. But when we do get a case it it’s important to take note of it – it becomes

part of the law that our practice and policy guidance needs to reflect, so we all need to be cognizant of the role of the courts.

Cases might be decided by either state courts or federal courts; which one is involved depends on a variety of things I won't go into. The cases listed on this slide are all from NC courts. Both the NC Court of Appeals and the NC Supreme Court have statewide jurisdiction, so when one of them decides a case that affects practice the effect is going to be felt throughout the state.

When we get a court case in this area, it usually addresses just one or two fairly narrow issues. This is because of how courts work – judges apply the law to the specific facts that a case presents and reach a conclusion about them. They don't give advisory opinions or comment on issues that aren't presented by the particular case.

In North Carolina, some of the significant cases we've had in the communicable disease law area include those that are listed here:

- A case in the 1990s upheld mandatory HIV reporting using individual's names. Those of you who have been around for a while may remember that long ago NC had anonymous HIV testing in which real names weren't reported, but the Commission's rules changed in the 90s to require actual names, which must be kept confidential.
- Our state's immunization requirements for children have also been upheld, as has public health's authority to enforce communicable disease laws.

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One more general thing I wanted to say about the law before we get into specific legal issues: in the United States, federal law is supreme – which means that federal law trumps conflicting state laws. Preemption is another word lawyers use to describe one law trumping another.

Much of communicable disease law is state law, not federal, so in the communicable disease law context the main issue affected by federal supremacy is confidentiality of information. There are both federal and state confidentiality laws that apply to communicable disease information. When they are incompatible, the federal law wins. By incompatible, I mean a situation in which it's impossible to comply with both federal and state law. If you have a situation like that, then federal law is the one you need to follow.

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Moving away now from a general discussion of the law, we're going to take a closer look at some key legal issues – specifically communicable disease reporting, investigations, control measures including isolation and quarantine, immunizations, enforcement. Before we dig into those, let's take a moment to consider the overarching issue of confidentiality.

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As we go through the key issues confidentiality is going to come up over and over, so I wanted to lay out the basic principles of confidentiality now and then get into more specifics as we look at each issue.

What the left side of this slide shows is that there are multiple sources of confidentiality laws: HIPAA, which is a federal law; state public health laws; and sometimes other federal or state laws come into play as well. All of these laws must be considered together to answer communicable disease confidentiality questions.

Some basic aspects of these laws that will come up in our discussion are outlined here.

First, HIPAA. This is our foundational law that makes protected health information confidential, and that includes individually identifiable communicable disease information. HIPAA has a lot of rules about when you can disclose information, but two that are really important to our discussion are the ones you see here: HIPAA specifically allows disclosure of information when a state law requires disclosure – and that's particularly important in the communicable disease context because we have a lot of state laws requiring disclosures about communicable disease. HIPAA also allows some disclosures that aren't required by state law but are permitted for certain public health purposes – that situation comes up sometimes in NC law but the first bullet point there is the really important one. If state law requires a disclosure, then HIPAA allows it.

Looking now at the bullet points next to the state law bracket, we have a number of state communicable disease laws requiring disclosure of information: we have mandatory reporting, access to records in outbreaks, and some mandatory sharing of immunization information too. State law also provides heightened protection to communicable disease information by restricting some re-disclosures.

Sometimes there are other laws affecting the confidentiality of communicable disease information. I won't inventory all of them for you today, but it's important to be aware that other laws are out there and when they apply to a situation you're dealing with they may alter usual practice.

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North Carolina law provides for both mandatory and voluntary communicable disease reporting, and both routine and non-routine reporting occasions. Most of what we're concerned with is mandatory routine reporting, so let's start with that, in the upper left part of the slide.

State laws require physicians and certain others to routinely report more than 70 communicable diseases and conditions. The list of reportable communicable diseases is adopted as a rule by the Commission for Public Health, and you can find it in the NC Administrative Code. The types of diseases on the list include those with public health significance such as tuberculosis, HIV, the various forms of hepatitis, most of the vaccine-preventable diseases, sexually transmitted diseases, foodborne, illnesses you might get from contaminated water, mosquito-borne, flu deaths and novel influenzas, and some others.

In addition to physicians, other people and entities who are required to make communicable disease reports include laboratories, school principals and child day care operators, and people in charge of restaurants (who are only required to make reports related to foodborne illnesses). School principals' ability to report is limited by a federal law call FERPA, but that law does allow them to make reports of illnesses that create a health or safety emergency in the school.

The law specifically gives the duty to report to physicians and doesn't mention other health care providers, but if another category of practitioner such as a nurse suspects a reportable communicable disease in a patient, that practitioner should notify the supervising physician to ensure the report is made. I'm aware that in some places there's a practice of delegating the duty to report, and I don't think that's problematic at all, so long as it's an appropriate person—by which I mean someone who can provide all the relevant information and has been included in confidentiality training and policies.

I think people are generally aware of mandatory routine reporting, but perhaps less aware of non-routine mandatory reporting. We have a state law that allows the State Health Director to issue a temporary order requiring health care providers to make certain kinds of reports. This type of order might require reporting a particular disease, or certain kinds of symptoms or trends in prescribing or other uses of health care services. This law was adopted to address emerging illnesses. For example, there might be a period of time during a new outbreak when we know something's going on but we aren't sure what it is yet and want to monitor symptoms while we figure it out – this is one way the state can gather information when something like that happens.

Usually we're concerned with mandatory reporting but the state does allow for some voluntary reporting as well. For example, we allow health care facilities to make reports but they don't have to – the physician is supposed to make the report, but this provides another route to get the information in if it doesn't come through a physician for some reason. We also allow voluntary reports of symptoms and the like so that a health care provider who sees something that he or she thinks may have been caused by bioterrorism can report it to public health, even if it's something that's not ordinarily reportable under the communicable disease laws – such as an exposure to a chemical.

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Here is a chart of who has to report what, when, and to whom, and it gives you the citations to the laws that impose the reporting requirement.

SLIDE 13

Do confidentiality laws prohibit communicable disease reporting that is required by law? Most of the time the answer is no. HIPAA allows reports to public health when a state law either requires or allows those reports, and everything we've discussed about reporting ties back to a state law that requires or allows disclosure to public health.

Even if HIPAA allows it, sometimes providers worry that their patients might sue them under some other law if they make a disease report. This need not be a concern, because state laws provide immunity from liability for disclosures of information that are made in accordance with the reporting laws.

And finally, a state law limits public health officials' re-disclosure of information that is reported, which provides additional confidentiality protection for communicable disease information. This doesn't mean public health officials can't re-disclose the information -- they can, but they have to follow state laws and rules that ensure the information is used for public health purposes, treatment purposes, and a few other things that are spelled out in the state statute cited in the last bullet point.

Earlier I said that confidentiality laws don't prohibit reports "most of the time." Let me elaborate on that a bit. HIPAA never prohibits a required reporter from making a report but sometimes other laws do. For example, school principals are required to report but they're also bound by FERPA, which is a different federal confidentiality law. Because of FERPA, they can make reports about diseases that create a health and safety emergency in the school—perhaps tuberculosis, or a foodborne illness that may have been spread at school, or pertussis or

measles—but they may not be able to report everything on the reportable disease list all of the time. It depends on whether the situation constitutes a health or safety emergency.

Sometimes other federal laws such as the substance abuse laws inhibit reporting as well.

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Our next topic is communicable disease investigations.

We have a state law that requires the local health director to investigate cases and outbreaks of communicable diseases and conditions. We also have some rules regarding investigation and there's a lot of practice experience with investigations – disease investigation specialists, communicable disease nurses, the communicable disease branch in Raleigh are all better sources for that type of information than I am.

I'm going to limit my comments to the single issue of access to records. There are all kinds of records public health officials may want access to as part of an investigation. Of course medical records are part of that, but there may be others too – maybe a restaurant's sales receipts when you're investigating a foodborne outbreak.

Health care providers and others are understandably cautious about giving public health officials access to their records and they often want to know what law gives you the authority to ask them for that. Here they are – two laws. The first one is general communicable disease investigations; the second is investigations that are tied to suspected bioterrorism. The slide specifically mentions health care provider records, but in the first law, the communicable disease law, the law refers both to health care providers and other persons. If you have a copy of the slides, you may want to write in "other persons" because that's where the authority comes from to obtain records from people other than health care providers. I apologize for that omission.

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However the health care providers are the ones who are likely to ask, what about HIPAA? Because if they let public health officials see their records, they're making a disclosure of protected health information and they can't do that unless HIPAA allows it.

Once again, the answer is HIPAA does allow it. HIPAA allows disclosures to public health that are required by state laws, and the laws cited on the previous slide are state laws requiring disclosure. Health care providers are immune from any other liability that might arise from

sharing the information with public health. In addition, public health has confidentiality laws and rules that limit how they can share the information further.

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Let's talk now about communicable disease control measures.

North Carolina has a state law that authorizes the Commission for Public Health to adopt rules prescribing control measures, and then it goes on to require all persons to comply with the control measures that the Commission adopts. The Commission's rules can be found in the NC Administrative Code; the citation is on the slide.

The rules specify the control measures for some diseases and conditions—namely, HIV, hepatitis B and C, STDs, TB, smallpox/vaccinia, and SARS. What this means is that you will find most of the specifics of what public health officials may require as control measures are spelled out in the rules themselves. Sometimes another document is mentioned in the rules as well – for example, the TB control measures tell you to follow the CDC's guidelines and recommended actions for control measures as well as what you can find in the rules themselves.

Now there are many more communicable diseases and conditions than those listed in the first bullet point – where do you find the control measures for those? The rules tell you to look to these sources:

- CDC guidelines and recommended actions should be the primary source.
- But if there isn't anything on point from the CDC, then the next source is the American Public Health Association's Control of Communicable Diseases manual, which is now in its 19th edition and is available in electronic formats as well as a book.

There are two specific issues related to control measures I want to say a little more about: first, isolation and quarantine, and second, the issue of control measures for emerging illnesses.

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Isolation and quarantine are really a subcategory of control measures, but they warrant stand-alone treatment because they have some unique qualities and some of their own laws as well.

These are the issues I'd like to address:

- What isolation and quarantine are, and how they differ
- Who has the authority to order isolation or quarantine

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- How long isolation or quarantine orders last
- And how isolation and quarantine can be enforced

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The key distinction between isolation and quarantine is that isolation is for sick people and quarantine is for exposed people.

North Carolina law embraces that distinction but adds a couple of things that are important to be aware of.

The first NC-specific addition is that our quarantine law mentions unimmunized persons. Specifically, it says that a person who has not been immunized may be quarantined during an outbreak of a vaccine-preventable disease, even if we don't have a particular reason to believe that person has already been exposed. This law could come into play if, for example, there was an outbreak of pertussis in a child day care center. Most children in child day care centers in NC should be immunized under our state laws, but some may not be because of religious or medical exemptions. Those children could not be required to be immunized, but under the quarantine law they could be required to stay away from the facility during the course of the outbreak.

The other somewhat unusual and important thing about NC isolation and quarantine laws is that they distinguish between freedom of movement and freedom of action. It's important to recognize this distinction because orders restricting freedom of movement have time limits and other constraints that don't apply to orders restricting freedom of action.

An order restricting freedom of movement tells a person to stay home or in a health care facility, or don't go to work or school, or otherwise restricts his or her ability to move about freely in society. We sometimes refer to this as physical isolation or quarantine.

An order restricting freedom of action doesn't affect where a person may go, but it restricts how the person behaves. It generally boils down to an order telling someone to comply with the control measures. For example, an order issued to a person with HIV may order the person to notify sexual partners, use condoms, refrain from sharing needles, all the other things that you'll find in the HIV control measures. Somewhat confusingly, we call this an isolation order in North Carolina—not because it physically isolates the person, it doesn't. But our law defines isolation to include limitations on freedom of action and so an order directing a person with a

communicable condition to behave (or refrain from behaving) in particular ways is called an isolation order.

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An isolation or quarantine order may be issued by either the local health director or the state health director. It doesn't have to be both and it usually isn't both. The health director may delegate the authority to order isolation to another appropriate person in the health department, and in fact it's a good idea to have a plan for delegating the authority so that it can be exercised by someone if the health director is unavailable when the authority is needed. Some of you may have developed delegation plans as part of your pandemic preparedness plans.

How long does the order last? That depends in part on whether the order limits freedom of movement or freedom of action. This is one of the reasons it's important to understand that distinction.

- If the order limits freedom of action, then it lasts as long as the public health is endangered and there's no other limit in the law.
- But if the order limits freedom of movement, it lasts as long as the public health is endangered or 30 days, whichever is less. If the order reaches the 30 day expiration and the public health is still endangered by the persons, the health director can ask a superior court judge to extend the order.

An isolation or quarantine order can be appealed by the person who is subject to it. If the order limits freedom of movement, there are specific procedures for how to appeal that are set out in a state statute, GS 130A-145(d).

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Here's an issue that has come up with outbreaks of new illnesses such as SARS and H1N1 flu.

You'll recall that all persons are required by law to comply with control measures. In the case of emerging illnesses, there aren't going to be any control measures in the administrative code, at least not at first, so we have to look to CDC guidelines and recommended actions. What tends to happen with emerging illnesses is that the control measures will evolve and change as understanding of the new illness develops. This makes sense but it gives us some legal problems.

For example, at the outset of the 2009 H1N1 outbreak CDC guidance advised school closure if any student or staff member developed the flu. But very shortly thereafter, CDC significantly modified its guidance on school closure. School closures still occurred in some places, but they were for operational reasons – because there were too many staff absences or similar concerns – they weren't ordered by public health as a control measure.

If you require someone to comply with control measures and the control measures change, you need to do two things.

First, you need to tell the person what the new control measures are and tell them to comply with the new ones from now on.

Second, when you give a person control measures for emerging illness you should keep a record of what the control measures are on the day you give them. If you're relying on CDC guidance, chances are you're getting that guidance electronically and that may mean you have to do a little extra to make sure you document it – especially if you're getting it from the web. Save a copy, date it, and make sure your records are clear that *that* was the CDC document you were relying on when you gave the person control measures. Then if you have to explain later why you ordered X when the CDC later decided that Y was the more appropriate control measure, you have the materials you need to explain why you did what you did when you did it.

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Turning now to NC's immunization laws:

There is a state statute that requires each child present in this state to be immunized according to a schedule adopted by the Commission for Public Health. The specific requirements and the schedule are in the NC Administrative Code. The citations to the statute and rules are on this slide.

This law requires all children to be immunized unless they qualify for an exemption.

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There are only two exemptions allowed under NC law: medical and religious. There is no personal belief or philosophical exemption in North Carolina.

To qualify for a medical exemption, the law says a child must have a condition that is recognized as a contraindication to immunization by the Advisory Committee on Immunization

Practices, and it must be certified by a licensed physician. Medical exemption forms are available through the state Immunization Branch's website, www.immunizenc.gov.

The other type of exemption allowed under NC law is a religious exemption. A child qualifies for this when his or her parent or guardian has a bona fide religious belief that is contrary to the immunization requirements. There is no form for claiming this exemption; the parent must write a statement of religious objection for the child. The law does not explain further what constitutes a bona fide religious belief, but we do have a state regulation that clarifies that this exemption is not intended to apply to beliefs that are not religious in nature.

The law says the child "shall be" exempt from the requirements if the parents have a religious objection, which suggests that public health officials don't have the discretion to deny an exemption when the objection is based on bona fide religious beliefs. The law does not answer the question of whether officials can deny request for exemption if they believe an objection is not grounded upon a religious belief. When that issue comes up, and it does from time to time, the public health official should consult with an attorney.

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Earlier I said that there is a state law that requires all persons to comply with communicable disease control measures. When we talk about enforcement of communicable control laws, that's usually the one we're talking about – the law that requires people to comply with control measures.

Here are the top five things to know about enforcement:

- While any violation of North Carolina communicable disease laws may be enforced using civil or criminal legal remedies, those remedies are most commonly used for violations of control measures. Theoretically, you could also use public health legal remedies to enforce the laws requiring physicians to report communicable diseases, or you could use them to enforce the immunization requirements, but those matters are usually handled in other ways.
- Second, it's almost always best to seek compliance through education first.
- Third, issue any written orders that may be appropriate before trying to enforce the laws in court. For example, if someone with HIV isn't complying with control measures, issue an HIV isolation order to that person before you take them to court over their noncompliance.

- Fourth, keep careful documentation of evidence of noncompliance.
- And fifth, if you decide you're going to court, seek the help of an attorney.

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Here are your basic enforcement options – one is criminal and one is civil.

Criminal: A person who doesn't comply with communicable disease control measures can be charged with a misdemeanor and can be sentenced for up to two years. There is more information about how to go through the process of charging someone with a misdemeanor on some materials I've developed that are available through this link, but I've highlighted one of the most important points on the slide here: work with your local district attorney's office in doing this. You'll most likely be working with an assistant district attorney, not the elected DA.

Civil: Another way to enforce the communicable disease laws is to ask a judge for an injunction. An injunction is basically an order that tells someone to stop doing what they're doing – in the communicable disease context you're telling them to STOP breaking the law and START following the control measures. They're supposed to do this anyway, but the value added by a court order is that you have the weight of the court behind that order. If someone is ordered by a judge to comply with the communicable disease laws and they continue not to comply, they're in contempt of court and the court may punish them for that. Again, there's more information about this remedy on-line, but here's a key point: work with your county attorney or health department attorney in doing this.

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Here we see our cross-cutting concern of confidentiality coming up again. There are two questions that I'm frequently asked about confidentiality and enforcement.

The first is whether public health officials may disclose confidential health information to the attorneys, magistrates, judges, and others who are necessarily involved in enforcement actions. The answer is yes; both HIPAA and state law allow those disclosures to be made.

The second question is; how can we limit the amount of information that gets entered into court records that become part of the public record? It is important to work with the attorney and court officials in doing this to ensure that their needs for the legal process are respected. For example, a magistrate who issues a criminal summons to a person who has violated the communicable disease laws must put enough information into that document to give the person adequate notice of what they're being charged with. However, that doesn't necessarily

mean that the magistrate must identify the specific communicable disease or condition – there are ways to word the document that make clear the person is being charged with violating communicable disease control measures without including that information.

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Our final topic is HIV testing. In North Carolina we have both a general statute and regulations in the Administrative Code that specifically address HIV testing

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In 2006, the CDC issued some new recommendations about HIV testing.

The CDC's overarching goal was to make HIV screening in health care settings a routine procedure, and it had the specific objectives that you see here:

- To increase screening in health care settings,
- Make early detection of HIV more likely,
- Identify and counsel people with unrecognized infection and link them to services, and
- Reduce perinatal transmission of HIV.

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Here are the citations to the NC laws that address HIV testing.

The statute was in place before the 2006 recommendations and has not been changed. This law establishes the general rule that informed consent is required for an HIV tests, but it allows for a couple of exceptions, and one of those exceptions is that the Commission for Public Health may adopt rules requiring tests.

The Commission has done that and we have rules that require tests in certain circumstances. In addition, after the CDC issued its recommendations in 2006, the rules were changed to allow HIV tests to be done pursuant to a general consent to treatment. Before that rule change providers routinely obtained special consent for HIV tests in a kind of opt-in model; now the rules allow it to be more of an opt-out.

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This slide compares the HIV test rules we had before the CDC recommendations of 2006 to the rules we have now. The old rules are on the left and the new rules are on the right.

Let's start by looking at the middle section of the slide. The statute that authorizes these rules establishes the general rule that informed consent is required for an HIV test, but the old rule didn't say anything about what form that consent had to be in. It was generally assumed that it needed to be specific and in writing. The rule change made clear that the test can be done pursuant to a general consent to treatment or lab tests – it doesn't have to specify HIV testing. However, the patient still must be notified that they're going to be tested for HIV and given the opportunity to say no. That notification can be given orally rather than in writing. This makes it more of an opt-out model for HIV consent.

The other changes to the rules affected pre-test and post-test counseling. Pre-test counseling is no longer required. Individualized post-test counseling is no longer required for people who have negative tests; however it is still required if the test is positive, and it must include referrals for treatment and information about HIV control measures.

These are the general rules that were designed to make HIV testing more routine, a part of ordinary care. In 2007 new rules regarding tests for pregnant women and newborns were also adopted. (next slide)

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Once again this slide shows the rules as they were before the CDC's 2006 recommendations were released, and how they are now. Let's focus on the right side, how they are now.

The new rules essentially require pregnant women to be tested for HIV. Physicians must offer the HIV test to women at their first prenatal visit and again in the third trimester, and then must conduct the test unless the woman refuses to agree to it after being told it's going to be performed and having a clear opportunity to refuse. However, if the woman has not yet been tested at the time of labor and delivery, the requirement that she be given an opportunity to refuse goes away. At that point, if there's no record of an HIV test result from a test performed during the current pregnancy, the physician must order the test to be performed without consent, if it can be done safely.

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If the mother is never successfully tested, then the rules require that the newborn be tested instead. In the middle box of the table on the right there's a quote here from that rule: "The fact that the mother has not been tested creates a reasonable suspicion ... that the newborn has HIV infection ..." The bottom right box explains the significance of the quoted statement: it suggests that a health care provider may test a newborn even if the parent refuses to give consent. That's an exception to the usual rule that you need the consent of a parent to perform an HIV test on a minor child who is incapable of giving consent on his or her own. Teenagers may be able to give consent on their own, but a newborn certainly can't.

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And that leads me into the final issue regarding HIV tests that I wanted to address today, and that's tests for minor children – people under the age of 18. As I just said the general rule is that you need the consent of a parent or guardian to test a minor for HIV. However, there are a couple of significant exceptions to that general rule.

The first is that some minors can consent on their own under NC's minor's consent law. To give effective consent, the minor must be capable of making his or her own health care decisions.

The second exception is in the HIV testing statute and it addresses the situation where a minor can't consent to the test on their own, the parent refuses to consent, and yet the physician has reason to believe the child should be tested – either because there's reason to suspect the minor actually has HIV or that the minor has been sexually abused. In a case like that, the physician must give the parent or guardian an opportunity to consent to the test, but if the parent refuses the physician can go ahead and test. A physician who does this should document that the parent was given the opportunity to consent and refused, and should also document his or her basis for concluding that the minor needed to be tested anyway because there was a reasonable suspicion that the minor has HIV or has been sexually abused.

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RESOURCES

- www.ncleg.net
North Carolina General Assembly website. Contains NC General Statutes, as well as legislation in progress (bills).

- <http://reports.oah.state.nc.us/ncac.asp>
North Carolina Administrative Code.
- www.ncphlaw.unc.edu
SOG website on North Carolina public health law. Click on Legal Information by Topic, then Communicable Disease.

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