ABSTRACT

State law is generally the controlling authority for whether parental consent is required or minors may consent for their own health care, including vaccination. At the federal level, no vaccination consent law exists; however, federal law requires that vaccine information statements be given to the parent or another person who is qualified under state law to consent to vaccination of a minor. All states allow minors to consent for their own health care in some circumstances on the basis of either (1) their status (eg, age, emancipation, marriage) or (2) the kind of health care services they are seeking (eg, family planning services, treatment of sexually transmitted disease). In each state, a specific analysis of laws will be required to determine the circumstances under which a minor can consent for vaccination.

Consent requirements for health care of minors in the United States derive from a complex patchwork of state and federal laws, including statutes and regulations, as well as judicial interpretations of the relevant statutory, regulatory, and constitutional provisions. When considering consent requirements for vaccination of adolescents, it is significant that some adolescents are legally minors and some are legally adults.

In general, consent for health care must be given by someone with the appropriate legal authority. An adolescent routinely obtains this legal authority when he or she reaches the age of majority and attains adult status. In most states, this age is 18 years. Adolescents who are legally adults are generally authorized to consent for their own care. For those adolescents under the age of majority who are legally minors, the consent of a parent, legal guardian, court, or some other individual authorized under state law is generally required.

Numerous exceptions to this basic rule allow health care to be provided to minors without the consent of a parent or guardian in specific circumstances. Every state has statutes that embody these exceptions, which are often referred to as “minor consent laws,” and many of these statutes have been in place for 3 or 4 decades. They fall into 2 general types: 1 that allows minors to consent on the basis of their legal status (Table 1) and 1 that allows them to consent for specific health services (Table 2).

The requirement to obtain consent has limited the success of vaccination programs that target adolescents outside the medical home, especially in school-based vaccination programs. Although the proportion of adolescents who do not return forms that were sent home to obtain parental consent and the reasons that these consent forms are not returned vary, a large proportion of adolescents do give their own consent for vaccinations when parental consent is not required.

In this article we provide a brief overview of the provisions of federal and state law that are relevant for determining who may consent for vaccination of adolescents and of the information currently available about how these laws have been interpreted and applied in practice. Many individuals and agencies involved in the implementation of adolescent vaccination programs are uncertain about the legal requirements for consent. As new vaccines
are developed and implemented for the adolescent population, it is important that health care providers and policy makers understand clearly the legal framework for consent and its application to vaccinations.

**FEDERAL LAW**

Federal law does not explicitly require parental consent for vaccinations. However, federal law does require the provision of information about particular vaccines when they are administered. This requirement is based on the National Childhood Vaccine Injury Act of 1986 (NCVIA), which requires the provision of a vaccine information statement (VIS) whenever any specified vaccine is administered to either a child or an adult. A VIS is a 1-page (2-sided) information sheet produced by the Centers for Disease Control and Prevention (CDC). VISs inform vaccine recipients, or their parents or legal representatives, about the benefits and risks of vaccines.\(^8\) The CDC’s VIS fact-sheet Web page (www.cdc.gov/vaccines/pubs/vis/vis-facts.htm) includes information on provider responsibilities, types of VISs and when to use them, how to get VISs, translations, and frequently asked questions.

Federal law requires that the VIS be provided to a patient (or, in the case of a minor, to the minor’s parent or legal representative) before each dose of each vaccine covered by the NCVIA, which includes all vaccines administered routinely to children and adolescents. Under CDC instructions for use of the VISs, the term “legal representative” means any person who is qualified under state law to consent to the vaccination of a minor child or incompetent adult.\(^8\)

Compliance with VIS requirements varies. Research on VISs has shown that they are provided to slightly less than two thirds of parents in private pediatric practices and to a somewhat higher proportion in the public sector.\(^9,10\) Provision of VISs is less consistent with adult patients.\(^11\) To achieve higher levels of compliance, some states impose stricter controls on the use of VISs beyond that imposed by federal regulations. For example, the state board of medical examiners in Oregon has warned that failure to provide a VIS may result in disciplinary action.\(^12\)

Consent is not addressed in the NCVIA. Consent for vaccination, as for other health care, is governed by state law. However, confusion sometimes arises among physicians or parents, who think that the VIS is a written informed consent form, although it is not. Rather, when written informed consent is obtained for vaccination, for whatever reason, the VIS is often provided together with that form.

**STATE LAW**

States generally do not have comprehensive statutes that specify consent requirements for vaccination of children, although some states have statutes or regulations that apply in specific circumstances. However, vaccination generally would be covered under laws that more generally address consent for health care and, on the basis of statutes and/or court decisions, every state requires minors to have parental consent for most health care, including vaccination.\(^2,13\) When the parent is not available or does not have custody, depending on the specifics of an individual state’s laws and the minor’s particular circumstances, consent for health care generally may almost always be given by a legal guardian or a court and may sometimes be given by related caretakers, foster parents, social workers, or probation officers, who have the appropriate authority. This would likely also be true for vaccination. With respect to vaccination, consent laws in a majority of states have been interpreted as requiring consent for each injection when more than 1 injection is required to complete a vaccination series.\(^13\)

The question of when adolescents may give consent for their own vaccination depends on an analysis of several factors: the age and capacity of the adolescent, the state in which the adolescent is seeking care, the legal status of the adolescent, the type of health care, and the disease for which vaccination is being administered. These factors are addressed in the minor consent laws, which are contained in 2 types of statutes in every state: laws that allow minors to give consent on the basis of their status (Table 1) and those that allow minors to give consent on the basis of the services they are seeking (Table 2).\(^1\) Both types of minor consent laws may be used to determine if an adolescent minor may consent for vaccination.\(^13\)
Minors who are generally allowed to consent for their own health care on the basis of their status (e.g., age, emancipation, marriage, living apart from parents) would likely be able to consent for their own vaccinations unless a specific law explicitly precluded them from doing so. The concept of the mature minor, which was developed in court decisions and is widely accepted by legal scholars and courts, enables certain older minors who have the capacity to give informed consent to do so for care that is within the mainstream of medical practice, not high risk, and provided in a nonnegligent manner. This doctrine also might provide a basis for a minor to give consent for vaccinations.

Laws related to care for sexually transmitted diseases (STDs) and reportable diseases may also be relevant to whether an adolescent minor may consent to vaccination, depending on the type of vaccine to be administered. Every state has a law that allows minors to consent for diagnosis or treatment for STDs (the terminology in some statutes is “venereal disease”). In addition, approximately one fourth of states explicitly allow minors to consent for diagnosis and treatment of reportable diseases. Some state laws include the term “prevention” along with “diagnosis” and “treatment,” which could allow the law to cover vaccinations for sexually transmitted or reportable diseases (e.g., hepatitis B). Other states do not include the term “prevention” among the services explicitly covered but use other terminology, such as “services related to the diagnosis or treatment of an STD or reportable disease,” that might justify a minor giving consent for a vaccination.

Ultimately, providers and public health officials in each state must understand the laws and interpretations in force in their state. Information about the minor consent laws in all 50 states and the District of Columbia is available from the Center for Adolescent Health and the Law (www.cahl.org) and the Guttmacher Institute (www.guttmacher.org). In addition, general counsel in state health departments may be able to assist state agencies with the interpretation of these laws.

CONCLUSIONS

The impact of federal and state law requirements on the success of vaccine implementation for vaccines for adolescents should be reviewed carefully. Legal interpretations and successful practices that have facilitated delivery of vaccines to adolescents in specific states or provider systems should be considered. The VIS, as required under federal law, should be used as a tool to make sure that the benefits and risks of vaccination are understood, and if necessary, providers should receive additional information and training in the use of VISs to make sure that they feel comfortable discussing the benefits and risks of vaccines with parents and adolescents. Where laws or policies include specific barriers (e.g., requiring a separate consent for each dose of the same vaccine), changes to those laws or policies (e.g., a single-consent approach to multiple-dose vaccines) could help to make sure that coverage among adolescents can be maximized. Ultimately, the goal of laws and policies at both the state and federal level should be to ensure that adolescents and their parents understand the risks and benefits of recommended vaccines; that parents have the opportunity to consent for the vaccines; that adolescent minors, in appropriate circumstances, be allowed to give consent for themselves; and that as many adolescents as possible receive the benefits of immunization against vaccine-preventable diseases.

REFERENCES


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