



ADA American Dental Association®

Legal, Insurance and Risk Management Considerations

HIPAA • Charitable Immunity Protection



Legal, Insurance and Risk Management Considerations

As with any access program, Give Kids A Smile® raises legal, insurance and risk management considerations. The good news is that these considerations can be managed with thoughtful planning. Here is a discussion of several key issues, along with some ways you might wish to address them.

Overview

With most access programs, the key risk is the same as in any practice setting: someone getting hurt. This could be a patient being injured as a result of receiving care; it could also be a patient, family member, treatment team member, access staff or volunteer sustaining an injury in connection with the program, such as a "slip and fall" incident on the way to or from treatment. Abandonment issues may also arise, particularly if there is any need for follow-up care after an "access day" visit. In addition, access programs and participating volunteers need to adhere to all applicable laws, such as those regarding anti-discrimination, record keeping, privacy, security, and fraud and abuse.

The potential malpractice risks associated with a dentist's participation in an access program, including Give Kids A Smile ("GKAS"), are generally insurable under professional liability insurance policies. Allied dental employees or volunteer staff members working at the direction of the dentist are also typically insured. For specific information about your personal coverage, including any limitations or requirements, it is advisable to discuss your plans with your insurance agent or company representative. We trust you'll find that your policy affords protection for you and your team members—so the opportunity is yours to simply volunteer!

Beyond insurance, it is worth noting the following with respect to managing the risks associated with access programs:

- Dentists routinely manage all of these risks in their daily practices.
- If an access program is properly structured, charitable immunity and volunteer protection laws may afford some liability protection to dental team volunteers.
- Dental access programs report they have effectively managed their risks (see below).

Safely Navigating the Dental Society's Role

What may be new with an access program is the dental society's role and potential liability exposure. In addition, the society's involvement may trigger additional legal and/or tax considerations, especially if the society wishes to incorporate its program as a non-profit organization. With the right help and planning, this situation also is readily manageable.

A dental society wishing to develop, promote and/or operate an access program can be well served by seeking legal counsel and insurance advice for its program from the very beginning of the planning stages. This can help the society avoid future challenges with respect to legal exposure, insurance and indemnity considerations, incorporating as a nonprofit organization and other issues. The extent of the society's involvement may affect its legal exposure. Then again, state law may provide some protection for access activities (see below), or the society may simply decide that the benefits of a well-run access program outweigh any legal risks.

Although liability considerations regarding access programs cannot be absolutely extinguished, a lawyer can help a dental society structure its access program to minimize potential risks, and an insurance advisor can help identify the appropriate coverage. For example, a lawyer might suggest ways to structure the program to minimize the society's liability exposure and the likelihood of being sued for a dentist's malpractice. This would include, for example, participation agreements, and consent and release forms. Similarly, an insurance agent could recommend coverage to be held by the society and any additional insured requirements. An agent may also recommend requiring participating volunteer dentists to submit evidence of their own malpractice insurance.

HIPAA

Patients' dental records and other patient information are subject to applicable state and federal laws and regulations, such as state dental practice laws and privacy and confidentiality laws (which may include state law or HIPAA or a combination of the two). Reviewing applicable legal requirements and implementing any necessary compliance program is an important element of the GKAS planning process.

A health care provider who qualifies as a HIPAA "covered entity" (or as a "business associate" of a HIPAA covered entity) must comply with HIPAA and with any state law that is more stringent than HIPAA. Health care providers who are not HIPAA covered entities or business associates must comply with applicable state privacy, confidentiality, and data security law.

HIPAA requirements in GKAS events will depend on which, if any, participants meet the HIPAA definition of a "covered entity," "workforce member," or "business associate."

Covered Entity. A HIPAA covered entity includes a person, business, or agency that furnishes, bills, or receives payment for health care in the normal course of business, and that has transmitted a covered transaction electronically (or used another entity, such as a clearinghouse, to conduct a covered electronic transaction on its behalf).

Workforce Member. Any person whose work is under the covered entity's direct control is a "workforce member," of the covered entity, whether or not the covered entity pays them. This includes employees, volunteers, trainees, and others. Covered entities are responsible for workforce HIPAA compliance.

Business Associate. A "business associate" is a person or entity (other than a workforce member) that performs, on behalf of a covered entity, a function or activity that involves protected health information. HIPAA requires covered entities and their business associates to enter into "business associate agreements" with certain required provisions.

If HIPAA applies, the covered entity or business associate must comply with the Privacy Rule, Security Rule and the Breach Notification Rule with respect to all of its protected health information (PHI), whether the PHI is electronic, written, oral, or in some other form.

The HIPAA Security Rule, which requires specified safeguards for electronic protected health information, is "scalable," which means that that the covered entity or business associate may take a flexible approach to protecting electronic data and implement security measures that are reasonable given its size, complexity, capabilities, and technical infrastructure, the cost of security measures, and the likelihood of potential risks.

Full face photographic images and any comparable images are HIPAA identifiers. A covered entity or business associate (or their workforce member or agent) who takes photos at a GKAS event should treat the photos as PHI and not release them unless both a signed release and a signed HIPAA valid authorization have been obtained for each patient in the photo. The forms should comply with both HIPAA and any applicable state law.

Some organizations believe that HIPAA status does not apply to covered entity dentists volunteering outside of their private practice. However, unless and until the enforcement agencies clarify otherwise, a straightforward reading of HIPAA suggests that covered entity status follows the dentist to any practice setting. The chart on the following page looks at the most likely scenarios, assuming that HIPAA status follows covered entities from private practice to volunteer activities outside their dental offices.

GKAS PATIENT SERVICES	<u>Covered Entity Dentists</u> (already subject to HIPAA)	<u>Non-Covered Entity Dentists</u> (not subject to HIPAA)
Dentist provides patient care in his or her private office	<p><i>Extend HIPAA compliance efforts</i></p> <p>The Privacy Rule - protects PHI using vehicles such as a Notice of Privacy Practices, and gives patients certain rights, such as a right to an accounting of disclosures of their PHI.</p> <p>The Security Rule - protects electronic PHI through the use of administrative, physical and technical safeguards, which can be incorporated into access programs conducted at covered entity dentist's office.</p> <p>The Breach Notification Rule - requires notification to individuals, HHS, and in some cases the media, if unsecured PHI is breached.</p>	<p><i>No required to comply with HIPAA, BUT...</i></p> <p>Dentists must comply with any applicable state privacy, confidentiality, and data security law.</p>
Dentist volunteers at a covered-entity operated facility	<p>If the facility is a HIPAA covered entity, following that facility's HIPAA policies and procedures is the simplest approach.</p> <p>Doing so can promote consistency in patient HIPAA protection and ward off inconsistent messages about privacy or security that might lead to complaints. The facility can inform you of its requirements.</p>	<p>A non-covered entity dentist volunteering in a covered entity facility will probably be asked, and should be ready to follow, the facility's HIPAA policies and procedures. The facility can advise dentists and the dental society of its requirements.</p>
Dentist volunteers at a non-covered entity facility	<p><i>Extend HIPAA compliance efforts!</i></p> <p>A covered entity dentist can bring copies of his or her Notice of Privacy Practices to the event, and try to keep patient information as private as reasonably possible under the circumstances. The dentist should also apply safeguards to electronic communications tools (e.g. laptop computers) brought from the office to the outside facility, in accordance with his or her Security policy.</p> <p>Appropriate privacy and security precautions should be taken if those tools will be used to send or otherwise share electronic protected health information of a GKAS program patient.</p> <p>A covered entity dentist who discovers a breach of unsecured PHI should provide notification as required by the Breach Notification Rule.</p>	<p><i>Not required to comply with HIPAA, BUT...</i></p> <p>Dentist must comply with any applicable state privacy, confidentiality, and data security law</p>

Summary:

Compliance. Dental societies promoting GKAS should raise the issue of compliance with HIPAA and any applicable state laws, such as confidentiality, privacy, and data security laws, and encourage participating dentists to ensure that they are in compliance with all applicable federal and state laws. Dental societies may facilitate HIPAA compliance by taking steps such as developing sample compliance materials. Any participant that qualifies as a business associate of a covered entity should enter into an appropriate business associate agreement.

Qualified legal counsel should be consulted to make sure that the program is structured appropriately to avoid noncompliance with federal and state fraud and abuse laws, such as the anti-kickback statute and beneficiary inducement prohibition in the Social Security Act. Under certain circumstances, offering free services to Medicare or Medicaid beneficiaries may risk violating these laws. Certain health care providers donating goods or services to a Federally Qualified Health Center may be required to meet the requirements of an anti-kickback safe harbor.

Photography. Anyone who intends to photograph a GKAS participant (including a dentist, patient, family member, or visitor) for publication or publicity purposes should secure a release in order to avoid a breach of privacy claim. If a patient is photographed by a covered entity or business associate (or their workforce member or agent), a simple HIPAA written authorization should also be secured permitting the disclosure of the images. A parent, guardian, or other legal representative generally must sign an authorization on behalf of a minor child.

Resources. For additional information:

- Federal and state laws pertaining to dental records, see ADA publication *Dental Records*: http://www.ada.org/prof/resources/topics/dentalpractice_dental_records.pdf. FQHCs contracts with private dental practitioners for dental services, see http://www.cdhp.org/resource/FQHC_Handbook
- A Roadmap for New Physicians on avoiding Medicare and Medicaid fraud and abuse, see <http://www.oig.hhs.gov/compliance/physician-education/index.asp> **OIG 2011** Advisory Opinion examining certain charity care arrangements, see <http://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-05.pdf>

Charitable Immunity Protection

One piece of particularly good news is that dentists who volunteer their services may have some protection against liability under state and federal laws. Many states have enacted charitable immunity laws that offer some legal protection to health care volunteers. Also, the Federal Volunteer Protection Act protects certain volunteer clinicians from claims of simple negligence. If the GKAS program involves a federal free clinic, volunteers at the clinic may or may not be afforded some protection under the Federal Tort Claims Act.¹ The ethical responsibilities of participating dentists must also be considered when analyzing the applicability of immunity laws. Risk management planning should involve an assessment of applicable laws and the impact on potential liability of the society and volunteers.

State Charitable Immunity Laws

According to a 2003 summary and analysis of those statutes prepared by Volunteers in Health Care (VIH), "Understanding Charitable Immunity Legislation: A Volunteers in Health Care Guide," charitable immunity laws in 43 states and the District of Columbia afford some protection for routine care provided

¹ For information about the application of the Federal Tort Claims Act to health centers, see U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA), FEDERAL TORT CLAIMS ACT HEALTH CENTER POLICY MANUAL (Jan. 3, 2011), available at <http://bphc.hrsa.gov/policiesregulations/policies/pdfs/pin201101manual.pdf>; see also Federal Tort Claims Act, 28 U.S.C. §2671.

by "clinician volunteers." Thirty-five of these state statutes refer specifically to health care provider volunteers and 21 states have legislation with specific reference to "dentists or dental care" (laws in other states may also apply to dentists, depending on their wording).

According to the VIH analysis, most states choose one of two routes to provide protection. Some change the negligence standard of care—that is, they raise the standard from simple negligence to gross negligence. Often called a "willful or wanton" or "reckless" standard, this approach makes it more difficult to prove negligence. Other states indemnify the volunteer clinician as if he or she were a government employee. Under this model, referred to as the "state tort claims act," the state establishes a legal defense fund to cover monetary damages as well as legal defense costs. Often these statutes cap the total compensation that can be paid for claims. Certain conditions may be specified, such as the setting in which the care is delivered or the existence of a formal agreement between the clinician provider and the state (see below). Several states combine aspects of both models.

VIH recognizes that neither of these approaches limits a patient's right to initiate a liability action against a volunteer or ensures that a lawsuit will be easily dismissed. But changing the negligence standard raises the bar for plaintiffs, and indemnity under a state tort claims act can help protect against financial loss.

Some states allow volunteers to purchase malpractice insurance through the state, or to purchase liability coverage at a discount. Eleven states have passed legislation specifically to encourage retirees to volunteer.

State laws may impose conditions in order for volunteer protection to apply. For example, there may be restrictions on the type of care provided, the care may need to take place in a certain setting, or patients may need to be notified of liability limitations. A dental society's lawyer can help assess the extent of available protections for an access program in a given state.

Dentists need to rely on qualified legal counsel for legal advice on applicable federal and state charitable immunity laws.

Volunteer Protection under Federal Law

The Volunteer Protection Act. The federal Volunteer Protection Act (VPA)² protects a volunteer clinician acting within his or her scope of duties in a government or nonprofit organization from liability for simple negligence. There are exceptions for misconduct related to crimes of violence, sexual offenses, civil rights violation, volunteers acting under the influence of alcohol, and other offenses. If a volunteer is held liable for gross negligence, the VPA limits the award of punitive damages to those cases in which there is clear and convincing evidence of willful or criminal misconduct or conscious, flagrant indifference to the rights or safety of the individual harmed. The VPA also limits awards for non-economic damages (pain and suffering) to the proportion of harm caused by the volunteer. The VPA preempts state laws that are inconsistent with the federal statute but does not preempt any state law that provides additional protection. The VPA permits states to pass laws that declare the VPA inapplicable in state court if all parties are citizens of the state. Like most state statutes, it does not limit the liability of the nonprofit organization through which the volunteer provides services. The VPA does not limit a plaintiff's right to bring suit, so a health care volunteer may still be exposed to legal defense costs.

Ethical Considerations

Statutory charitable immunity protections may not necessarily extend to a claim of abandonment. Consider, for example, the provision of preliminary care on an access day that specifically contemplates follow-up care to complete a procedure, or care with unexpected outcomes that require correction. The most prudent course is to make such care available to those who need it, even if that means providing care at the dentist's private practice, for free, and relying on malpractice coverage for protection. Situations like these can be anticipated in advance in consent and release forms that patients in access programs may be asked to sign; such forms should be shaped to protect the dental team to the extent

² Volunteer Protection Act of 1997, 42 U.S.C. § 14501.

possible by taking advantage of any charitable immunity protections afforded in the state where care is being provided.

Before considering to how to invoke state and federal legal immunity protections, participants in access programs, as in all patient care, need to keep in mind their ethical responsibilities in the ADA Principles of Ethics and Code of Professional Conduct (the ADA Code). By their very nature, access programs that serve vulnerable populations work to fulfill ethical responsibilities. Among other things, the ADA Code calls on dentists to promote patient welfare and embodies the concept of a single ethical standard, as reflected in Section 3, Beneficence:

. . . The dentist has a duty to promote the patient's welfare. This principle expresses the concept that professionals have a duty to act for the benefit of others. Under this principle, the dentist's primary obligation is service to the patient and the public-at-large. The most important aspect of this obligation is the competent and timely delivery of dental care within the bounds of clinical circumstances presented by the patient, with due consideration being given to the needs, desires and values of the patient. The same ethical considerations apply whether the dentist engages in fee-for-service, managed care or some other practice arrangement. Dentists may choose to enter into contracts governing the provision of care to a group of patients; however, contract obligations do not excuse dentists from their ethical duty to put the patient's welfare first.

Without a doubt, access programs serve to promote patient and public welfare. Dentists participating in access programs utilize their professional knowledge, skills and experience to improve the dental health of the public and elevate esteem for the profession. This fulfills the ethical obligation of community service as expressed in Section 3A of the ADA Code. Moreover, access programs advance the ethical principle of justice, which in its broadest sense calls on the profession to seek allies throughout society on specific activities that will help improve access to care for all (Section 4 of the ADA Code). Dentists must simply keep in mind the need to satisfy the "single ethical standard" contemplated in the Code even if they wish to rely on charitable immunity law protections.

Summary

Charitable immunity protections typically protect only volunteers acting within the scope of their responsibilities at the nonprofit organization (or governmental entity) at the time of their alleged acts or omissions, although some may extend protection for volunteers who are not part of an organized effort. For this reason, state or local dental societies sponsoring access programs may wish to register dental team participants and define their scope of responsibility. In addition, state statutes have various conditions that must be met to trigger immunity. For example, most do not provide protection for care in a dentist's own office. Some laws may restrict the type of care to which protection applies. Some impose patient notification of liability limitations, with state variations requiring written notice, specific language in the notice, language easily understood by individuals with limited education (e.g., 6th grade level in Michigan), or even a posting of a notice. Assessing the impact of applicable laws should be part of the GKAS risk management planning process.

Forms

Exactly what forms should be used to obtain consent and, to the extent possible, release from liability? Due to differences in state law, there is not a one-size-fits-all form that can be suggested for national use. There are, however, some things that can be kept in mind by access programs seeking to develop forms, including state-specific information on:

- **Informed consent**—whatever typically may be required as a matter of state law for paying patients, unless your state requires less for access programs. Be cautious about requiring written consent if it would not be required of the typical paying patient.
- **Malpractice**—release in accordance with any applicable state charitable immunity protection (some states require notice to patients, for example, how their rights and remedies may be limited in comparison to a typical malpractice case). Think through whether unintended consequences of a release form effectively saying "Dear Patient, by getting care here you're waiving many of your

- rights..." and ask whether it is worth any protections your state charitable immunity law may provide, especially if the risk **can** be managed in other ways, (for example, through insurance).
- **Abandonment**—same as malpractice, plus any information about how any follow-up care will be provided. It may be prudent to establish in the form that the provision of limited care at an access program does not establish a continuing doctor-patient relationship for other purposes

Sample forms used by well-known access programs across the country are attached to facilitate the development of forms for your access program. Of course, you will need to tailor your forms to your program design and needs and to satisfy the laws of your state.

Forms used in an access program, along with records reflecting patient care, should be completed and maintained in accordance with applicable laws. At a minimum, generally accepted record-keeping practices should be followed, unless state law allows for a lesser requirement for access programs; even then, good risk management may dictate following generally accepted practices.

Case Studies

As noted above, each access program is different, will raise its own set of legal and insurance issues, and is likely to be governed in certain respects by its own state law. Thus, there is no one-size-fits-all legal approach to managing those issues. Rather, each access program should be tailored to meet its own needs and objectives and to invoke legal and insurance protections as appropriate. With that in mind, let's take a look at how some highly visible access programs have reportedly managed their risks.

St. Louis, Missouri Give Kids A Smile Program: All dentist volunteers are licensed in the state of Missouri and have their own malpractice insurance. Give Kids A Smile, Inc is a functioning not-for-profit 501 (c) (3) that provides event liability insurance at the St. Louis University facility within its own insurance coverage costs. As they exit the facility, parents and caregivers are given a letter with an emergency contact number that is also included in the Give Kids A Smile office phone answering service. In addition follow-up procedures for the care of their child are included with the walkout statement of procedures placed in each child's take-home bag. Children needing more extensive dental procedures are given information about our Smile Factories program and also given a list of Medicaid providers in the area.

Virginia, Missions of Mercy (MOM Project): The Virginia Dental Association (VDA) advises its members to contact their malpractice providers to notify them that they are providing care in a different setting and under different circumstances. In addition, all patients/guardians sign a consent and waiver release prior to treatment. Local dentists in the MOM Project geographic area are asked to provide follow up care for a period of one week. In November of 2000, the VDA received an Attorney General's opinion from Mark Earley, then Attorney General of the Commonwealth of Virginia: "Therefore, it is my opinion that dentists who provide free dental services for the Mission of Mercy project are only liable for civil damages when their acts or omissions result from gross negligence or willful misconduct." In addition, the VDA sought an opinion from its personal attorney who agreed that the statute's meaning (54.1-106(A)) was clear in its intent and that under the MOM Project, licensed providers would be covered. Finally, the Missions of Mercy clinic takes advantage of a voluntary liability plan available to Virginia's free clinics as defined in § 2.2-1839 of the Code of Virginia. This program offers coverage for a variety of exposures including general liability, errors and omissions and medical malpractice. VDA submits the names of licensed volunteers to the state office of risk management, which oversees the liability plan program.

Conclusion

Potential risks associated with access programs are real but can be effectively managed. Securing sound professional advice, including advice from your attorney or malpractice carrier as appropriate, can help shape a successful program for all concerned. Keep in mind that both federal and state law will play a key role in decision-making. Among the factors to consider, think about whether the program sponsor wishes to invoke the protections of charitable immunity laws and, if so, assess whether the benefits and state law obligations make doing so worthwhile, particularly if the potential liability risk can be insured.

While this guidance attempts to provide dental societies planning an access event with information to help them develop compliance and risk management plans, it should not be treated as legal advice. Dental access programs vary widely, and each should adapt the suggestions in this guidance to meet applicable state and federal laws and regulations and the circumstances they are likely to encounter. Dental societies should seek legal advice from qualified attorneys on specific matters affecting their program, such as risk management, patient records, privacy, confidentiality, and data security laws and regulations (including state law as well as HIPAA as amended by the HITECH Act), and state and federal charitable immunity protection.

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This material is educational only, does not constitute legal advice. Dentists and dental societies should contact qualified attorneys for legal advice pertaining to issues arising in connection with access programs, including risk management, state and federal laws regarding privacy, confidentiality, and data security, including HIPAA compliance and the ARRA/HITECH Act, and volunteer protection and charitable immunity. (July 14, 2011)