

Organ Donation and the Principles of Gift Law

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The legal framework governing organ donation in the United States is built on principles uniquely designed to support the system of transplantation. Understanding how the laws are designed and operate in practice provides insight into organ donation practices and performance and illuminates how the law is utilized to drive change in the field.

The primary law governing organ donation in the United States is the Uniform Anatomical Gift Act (UAGA) (1). The UAGA is a model legislation drafted by the Uniform Commissioners that is then passed into law state by state. The Uniform Commissioners are a body of law and policy experts appointed by the governors of each state to identify areas that would benefit from uniformity nationwide but which cannot be federally regulated because they fall under the reserved powers of the state (2). Organ donation is one of those areas. The experience and policy of deceased organ donation should be consistent throughout the country regardless of what state you live or die in. Because matters of public health, contracts/gifting, and estate are reserved powers for the state to regulate, so too is organ donation, which involves components of each of those areas. Recognizing the need for a single approach to organ donation policy, the UAGA has been enacted in every state in the United States, providing national consistency through state law.

The UAGA establishes gift law as the central legal principle in the United States opt-in system of organ donation (1). The choice of gift law is significant. Because medical providers are trained in the central health law doctrine of informed consent, they are often surprised to learn that organ donation laws do not follow the same legal principle. Informed consent is the concept of permission granted by a patient for a particular treatment after a facilitated understanding of risks and benefits including available alternatives. Deceased donation, however, presents neither risks nor benefits to the donor because the donation occurs after death. Moreover, individuals provide permission for donation in advance of death (often years or decades), making it unknowable what organs or tissue will be suitable to actually donate at the time of death. For these reasons, informed consent as a legal structure is ill-suited for the regulation of organ donation. Alternatively, gift law provides the legal framework under the UAGA (3).

A gift—in legal terms—is the legally binding voluntary transfer of something from the donor to the donee

without payment (4). The lack of monetary exchange is important in this context because federal law prohibits the purchase or sale of organs (5). Consequently, ordinary contract law would be an inappropriate legal framework for organ donation because for a contract to be legally binding, there must be “consideration” (payment for the promise to transfer something from one individual to another). Note that donation and transplantation professionals are paid for their services as this is excluded from the federal prohibition, and because under the UAGA the donee of the anatomic gift is the transplant recipient, such payments do not abrogate the legal construct of organ donation as a gift. Clarity that transfer of organs from donors to recipients is legally binding is required as a matter of policy; the entire system depends on it. Gift law provides the legal certainty required and fits with the reality of deceased organ donation as a decision distinguished from typical health care decisions.

Gift law requires three basic elements: donative intent, transfer, and acceptance (4). Fulfillment of these elements results in a legally binding transfer of a gift from the donor to the recipient. Donative intent under the UAGA can be fulfilled either by an adult before death or a surrogate (next of kin) at the time of the donor’s death.

Because the UAGA does not incorporate an informed consent standard, donation professionals utilize the term “authorization” versus “consent.” Although both terms mean legal permission, this distinction aligns the terminology with the underlying legal principles. An individual authorizes an anatomic gift whereas a patient provides informed consent for a medical treatment.

Authorizing Donation: Two Bites of the Apple

Under the UAGA, an individual can make a gift before death or a surrogate can authorize a gift at the time of the donor’s death. In this manner, the UAGA provides “two bites of the apple.” This is an important legal component of the system because it provides two different legal avenues to arrive at a “yes” to donation.

First-person authorization is the term used when an individual authorizes their own anatomic gift before death, usually through a donor registry. Donor registries are registries of anatomic gifts. From a legal perspective, the donor registration process is not an informed consent process because it is not designed to be one and it is not required to be one under the law. The donor registration process meets the gift law standard under

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the UAGA. An adult individual can make a gift by registering as a donor or can decide not to make a gift.

Donor registries have been successful, with annual growth for the past 10 years and over 142 million registered donors as of January 2018, representing over 54% of the adult population (6,7). If an individual is registered, there is legally binding permission for donation at the time of the donor's death under the UAGA, and family members do not have the right to override this decision (1). This is not only the law, as in current practice most donations proceed even over family objection (3). The ability to move forward in these circumstances is supported by a measure of confidence that making an anatomic gift was the individual donor's affirmative decision—a voluntary exercise of autonomy under constructs of law and medical ethics. In the rare case where a donation from a registered donor does not proceed over family objection, it is usually because of marginal transplant potential or unusual circumstances regarding the registration. In such cases, from a legal perspective, the gift is not revoked, rather there is no transfer or acceptance (the second and third element under gift law).

The number of registered donors is only half the story. The donation rate is not 54%, rather the donor registration rate is 54%. The UAGA also permits surrogates to authorize donation at the time of an individual's death, providing a second opportunity to obtain a "yes". Because only a small percentage of deaths are eligible for donation for transplant, it is a very small number of surrogates that are ever approached for donation permission. Of that group, over half authorize donation. As a result, the donation rate (actual donors over eligible donors, defined by federal policy) is over 75% (8). The definition of eligible in the denominator of the donation rate as a proxy for medical suitability is currently the subject of national conversation. This should change over time, as medical advances and critical need result in transplantation of organs from increasingly complex donors (*e.g.*, HCV-positive donors) given the risk-to-benefit ratio of waitlist mortality versus transplant outcomes. The numerator of the donation rate is a composite: about half of donors previously authorized their own donation through a registry and surrogates authorize slightly more than 50% of the remaining half.

The UAGA establishes three legally recognized positions: (1) authorized gift, (2) no decision, and (3) refusal to make a gift. Before death, an individual can move between these three positions. A registered donor is in the positive position, *i.e.*, an anatomic gift has been authorized. If registration is then revoked, the individual moves back to the neutral position. Revocation is legally equivalent to having never made a gift. The UAGA does not provide for inference of intent from a revocation. A previous revocation does not bar a surrogate from authorizing an anatomic gift at the time of the individual's death (1). If an individual does not want to be a donor, the UAGA recognizes that only through a refusal (1). A refusal can be made through a signed document (*e.g.*, advanced directive) and is legally binding.

The opportunity to approach surrogates for permission when the donor has neither made a gift nor registered a refusal is an important component of the system. This is particularly true for some segments of the population

where registration rates are lower because of a preference for the family to make the donation decision at the time of death.

The UAGA Works for the United States

United States culture is deeply steeped in individual rights, starting with the Constitution and mirrored through the many laws, regulations, and cultural norms that prioritize individual autonomy. A rights-based culture is well matched with the UAGA legal framework requiring an affirmative, voluntary decision to make a gift. Under this opt-in policy, the United States experienced over 27% growth in deceased organ donors and transplants in the past 10 years (9) and measures favorably worldwide. Some areas of the United States significantly exceed the donation rate in Spain, which is widely regarded as the world leader (10). Although there is more that can and must be done to continue to increase the number of donors and available organs in the United States, the UAGA provides a good framework, on the basis of sound legal principles, to support that goal.

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Disclosures

None.

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