

**Risk-Sharing or Refund Programs in Assisted Reproduction**  
**By the ASRM Ethics Committee**  
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Some assisted reproduction programs now offer in vitro fertilization (IVF) on a “risk-sharing,” “warranty,” “refund,” or “outcome” basis, in addition to traditional fee-for-service pricing. Initially, risk-sharing patients pay a higher fee. If a risk-sharing patient achieves an ongoing pregnancy or delivery, the provider keeps the entire fee. If treatment fails, however, 90% to 100% of the fee is returned. Pretreatment screening costs, which can be considerable, and the costs of drugs are ordinarily not covered in these plans.

Such programs have been criticized as being exploitative, misleading, and contrary to long-standing professional norms against charging contingent fees for medical services. Proponents, on the other hand, argue that this form of payment is a legitimate response to the lack of health insurance coverage for IVF and to patient concerns about the high cost and substantial risk of IVF failure. If IVF fails in these programs, the patient is still left with resources to pursue other options such as adoption.

In assessing such programs, the Committee focused on the impact of such plans on patients, and not on the profit motive or entrepreneurial impulse that may also have motivated their emergence. It concluded that such plans are in principle ethically acceptable, but that great care is needed in their implementation to ensure that patients are fully aware of the advantages and disadvantages of risk-sharing programs, including the likelihood of success, the costs that are not covered, and the incentives that providers offering this plan have to take risks to assure success.

The Committee found that risk-sharing programs may be viewed as a form of insurance against the risk of failure of IVF that might appeal to some couples seeking IVF. The appeal arises from the absence generally of health insurance coverage for IVF, and the loss which treatment failure causes couples who purchase IVF with their own funds. Although both insured and uninsured patients experience disappointment when a treatment cycle fails, those patients who have paid for IVF out of their own pocket have also paid a substantial financial cost.

Risk-sharing programs are likely to appeal to this group of patients. In exchange for a higher fee, risk-sharing programs agree to provide a set number of IVF cycles to eligible patients. If IVF is successful, the program keeps the entire amount. If no pregnancy or delivery occurs, the patient receives a refund of 90% to 100% of the fee (exclusive of screening and medication costs). The nonrefundable fees in successful cases are intended to cover the cost of refunds to unsuccessful patients.

One set of ethical concerns raised about risk-sharing programs is that they are misleading or exploitive in that they induce patients who are desperate to have a child into purchasing a more expensive form of IVF service than is necessary. The Committee found, however, that the plans it examined provided sufficient information to enable patients to make an informed choice about whether to choose this option. For example, patients who meet program qualifications for these plans should know that they are otherwise good candidates for successful IVF, and thus might not need to purchase this

form of insurance. Also, while there are difficulties with patients comparing clinics in terms of efficacy, those problems exist independently of financial arrangements such as shared risk.

A second set of ethical concerns has arisen because risk-sharing programs appear to violate long-standing ethical prohibitions against paying contingency fees in medicine. This concern is based on Opinion 6.01 of the AMA Code of Medical Ethics, which states that “a physician’s fee should not be made contingent on the successful outcome of medical treatment (1).” However, neither of the two reasons given in support of Opinion 6.01 applies to IVF risk-sharing plans.

The first reason given is to discourage doctors from making their professional fees contingent on the success of a patient’s pending medical malpractice or worker’s compensation claim, thereby skewing the medical opinion which they render in such a case (2). But this concern has no bearing on the propriety of risk-sharing plans for IVF services, for they make fees contingent on the outcome of the treatment itself, not on the outcome of a lawsuit.

The second reason cited in support of Opinion 6.01 is that hinging fees on the success of medical treatment implies that “successful outcomes from treatment are guaranteed, thus creating unrealistic expectations of medicine and false promises to consumers.” While it is unethical to create unrealistic expectations or make false promises, risk-sharing plans do not appear to have that intent or effect. Providers charge a substantial premium to

those who enter the plan, compared to their conventional fee-for-service charge. While the provider's willingness to assume some of the risk of failure may convey a message of confidence in its services, no patient is likely to interpret the arrangement as a guarantee of success. On the contrary, the substantial "premium" built into risk-sharing fees signals to the patient that the provider needs to be compensated for assuming some of the risk of failure precisely because there is a significant risk that treatment will fail. What is guaranteed is obviously not success, but a refund if treatment fails.

Another rationale, not mentioned in Opinion 6.01, that might justify an ethical objection to contingent fees in medicine is that it is often hard to define medical success and determine whether it has occurred in a given case. Where the measure of success is not clearly specifiable, contingent fees will inevitably spawn doctor-patient disputes over whether a fee has been earned. But this rationale also is inapplicable to IVF risk-sharing plans, where measures of success are clearly stated, either delivery of a child or a pregnancy of specified duration.

A third set of concerns is that such programs have a built-in conflict of interest which is likely to skew clinical decision-making toward achieving pregnancy regardless of the impact on the patient in order to avoid paying a refund. Two such dangers may be cited. One is that the provider will be biased in favor of stimulation protocols that tend to produce more oocytes but pose relatively large risks to the woman's health. The other is that the provider will be biased in favor of transferring a relatively large number of

embryos, thereby increasing the likelihood not only of pregnancy but of multiple gestation, which can harm women, fetuses, and potential offspring.

The Committee recognizes this potential danger, but has not seen any evidence that either danger has materialized. It also noted that non-risk-sharing fee-for-service programs also have incentives to overstimulate the ovaries or transfer multiple embryos in order to have high enough success rates to attract future patients. The Committee did not find that the incentives are so much greater in risk-sharing plans that they deserve condemnation independently of comparable risks in fee-for-service plans. In both cases the ethical solution is to assure that patients are provided with reliable information about their chances of success, and the costs and benefits of different financing arrangements.

#### Conclusion

The Committee finds that the risk-sharing form of payment for IVF is an option that might be ethically offered to patients without health insurance coverage for IVF if certain conditions that protect patient interests are met. These conditions are that the criterion of success is clearly specified, that patients are fully informed of the financial costs and advantages and disadvantages of such programs, that informed consent materials clearly inform patients of their chances of success if found eligible for the risk-sharing program, and that the program is not guaranteeing pregnancy and delivery. It should also be clear to patients that they will be paying a higher cost for IVF if they in fact succeed on the first or second cycle than if they had not chosen the risk-sharing program, and that, in any event, the costs of screening and drugs are not included.

The Committee was especially concerned about the incentives that risk-sharing programs create for providers to take actions that might harm patients in order to achieve success and avoid a refund. For risk-sharing programs to be ethical, it is imperative that patients be aware of this potential conflict of interest, and that risk-sharing programs not over-stimulate patients to obtain a large supply of eggs or transfer more embryos than is safe for the patient, fetus, and prospective offspring. Patients should be fully informed of the risks of multifetal gestation for mother and fetus, and have had ample time to discuss and consider them prior to egg retrieval.

### **References**

1. American Medical Association, Council on Ethical and Judicial Affairs, Code of Medical Ethics 94-95 (1997).
2. Id.