

Value-Based Purchasing: Laws and Regulations

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Value-Based Purchasing Raises Legal Issues

- **United States Constitution**
- **Medicare law**
- **Federal Acquisition Regulations**
- **Privacy Act**
- **Freedom of Information Act**
- **HIPAA Privacy Regulations**
- **the antitrust laws**
- **the bribe and kickback prohibition**
- **the self-referral prohibition**
- **the prohibition against inducements to reduce services for beneficiaries**
- **state laws regulating physician practices and managed care**

Any changes must be constitutional

- **The Fifth Amendment provides “No person shall be ... deprived of life, liberty, or property, without due process of law.”**
- **Providers have a liberty interest in not having their reputations impugned by Medicare without an opportunity to respond.**
- **But due process can be very flexible.**

The Medicare statute

- **The ability of the traditional Medicare program to move to value purchasing is greatly limited by the nature, structure, and terms of the Medicare statute.**
- **In particular, statutes prescribing particular prospective payment or fee schedule payment schemes will have to be amended.**

Public reporting of quality data also raises legal issues

- Privacy Act of 1974
- Freedom of Information Act
- HIPAA Privacy Regulations

Accountable care organizations and medical homes also face legal issues

- Antitrust law
 - Entities must comply with network joint-venture safe harbor
 - Or be sufficiently integrated clinically to fit within the “rule of reason
- Stark self-referral prohibition
 - May be problem if ACO includes physicians and providers
 - Could be addressed by regulation

ACO legal issues

- Antikickback prohibition
 - Forbids remuneration for referrals
 - Could be addressed by regulatory safe harbor
- Inducement to reduce services prohibition
 - Basis of concern about gain-sharing
- State laws regulating groups and networks
 - Could be preempted by federal law for Medicare
 - But would limit non-Medicare uses of ACOs

Conclusion

- Implementing value purchasing in traditional Medicare will require legal change