

Value-Based Contracting: Supporting New Payment Arrangements

Value-based contracting for biopharmaceuticals is in its early stages, and the consensus among expert panels convened by NEHI is that thoughtful experimentation in these contracts should proceed. NEHI recommends a combination of strategies to foster innovation and experimentation, address operational challenges, undertake appropriate legislative or regulatory relief, and anticipate broader challenges stemming from a coming wave of high-cost therapies.

- 1 CONSENSUS DEFINITION:** Stakeholders should develop a consensus definition of value-based contracts, including contract parameters that will qualify a contract for appropriate protections under federal law and regulation.
- 2 GOVERNMENT HEALTH PROGRAM DRUG PRICE REGULATION:** CMS should provide reasonable accommodation under Medicaid Best Price and related regulations to allow for thoughtful experimentation with value-based contracts (e.g., to allow “money-back guarantee” or “no charge” contracts without triggering mandatory government price reductions).
- 3 ANTI-KICKBACK STATUTE:** The Office of the HHS Inspector General should create appropriate safe harbor protections that would allow biopharmaceutical manufacturers to undertake three types of activities in support of value-based contracting: provide data and analytics, make warranties of performance, and supply medication adherence support services and interventions.
- 4 FDA & COMMUNICATIONS:** The FDA should finalize guidance on pre-approval communications from manufacturers to payers and communications about cost-related data (“health care economic information”). The FDA should also consider issuing guidelines for communication of off-label information that is consistent with approved uses of a drug – for example, information about patient-reported outcomes.
- 5 DATA EXCHANGE:** The HHS Office of Civil Rights should provide guidance on exchange of protected health information, in compliance with HIPAA, that is needed to execute value-based contracts.
- 6 ANTICIPATING CHALLENGES:** Congress should request a National Academy of Medicine study to consider other potentially complementary approaches for financing high-cost, breakthrough therapies.

