



## Health Policy Stakeholder Meeting Template

In order to accurately capture and understand your organization's priorities for health care reform and other health care policy issues, we ask that you briefly detail your priorities as follows:

- Health policy priorities/goals in the short term

### 1. Enactment of a health reform program that:

- Provides quality, affordable health insurance for all
- Improves quality and slows health cost growth
- Enhances productivity and economic growth through prevention and better treatments for and management of chronic diseases and disability
- Maintains and encourages innovation
  - No centralized decision-making on individual procedures, drugs or devices
  - No use of cost-effectiveness to determine coverage or payment under Medicare, Medicaid or other programs

### 2. Restoration of public confidence in the FDA

- Prompt appointment of a respected, effective commissioner with an impeccable reputation as a scientist, manager and leader. Substantial increase in FDA appropriations in an early supplemental.

### 3. Additional goals and concerns

#### Financing

- Avoid implementation of a broad "gainsharing" program until current demonstrations are completed and can be evaluated (regulatory/legislative, regulation comment period on potential expansion closing in February).
- Enactment of a comparative effectiveness research program that focuses on clinical effectiveness, is open and transparent, and uses results to inform patients and physicians (legislative).
- No further imaging cuts (legislative, regulatory)
- Pay-for-performance, with appropriate provisions to assure quality and foster continued innovation (legislative)
- Assure that any movement toward "bundled" payments protects quality and innovation.
- Better reimbursement system for molecular and other novel diagnostic tests (regulatory/legislative)
- Coverage of remote monitoring services (regulatory/legislative)



- Advanced medical devices are not treated as commodities, i.e., concerns about competitive bidding

#### FDA

- Maintenance of existing preemption for PMA devices (legislative)
- MOA agreements on information-sharing with foreign governments (industry consultation during negotiations/protection of intellectual property)
- Maintenance of 510(k) regulatory structure (legislative)
- Greater use of ISO 13485 inspections to supplement FDA inspections/no new user fees (regulatory)
- Streamlined and modernized uniform approval system for in vitro diagnostic tests (regulatory)

#### Other

- Enactment of physician payment disclosure with Federal preemption (legislative)
  - Maintenance of broad current authority for device DTC advertising (legislative)
  - Access to capital for emerging growth companies, particularly in light of significant contractions of individual investor, venture capital, and credit markets. Address, in part, by inclusion in the stimulus of targeted tax incentives, e.g., allowing immediate access to net operating loss credits for such companies, and increase funding for NIH SBIR program.
  - Maintain a patent system that protects the value of investment in new medical technology
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- Health policy priorities/goals in the long term
    - Transparency in regulatory, coverage, and payment decision-making
    - Reduction in time required for development, regulatory approval, coverage and diffusion of new treatments and cures
    - Continued medical progress in preventing disease, detecting it earlier, and treating it more efficiently and effectively

