AdvaMed Priority Issues

Washington, D.C.
June 22, 2017
Federal Priorities

- Medical Device Tax
- MDUFA
- Breakthrough Pathway
Medical Device Tax

• Full repeal included in health care reform
  – H.R. 1628, the American Health Care Act of 2017
  – Anticipate repeal will be included in Senate bill

• CBO score could impact repeal inclusion
  – Higher than expected coverage losses
  – Lower total savings
    • Both would require additional votes

• Effective Date
  – January 1, 2018
MDUFA

- FDA Reauthorization Act of 2017 passed key committees
  - H.R. 2430; Passed House E&C 54-0; S. 943; Passed Senate HELP 21-2

- Key policy riders
  - Included in both House & Senate versions
    - Accessories
      - Streamlines classification process for accessories
    - Inspections
      - Reforms device inspection process
    - Contrast agents
      - Change regulation of contrast agents used in imaging devices
  - Included in one chamber
    - Diagnostics reform (Senate version)
      - FDA guidance on regulation of instrument families
    - Third Party Servicing (House version)
      - FDA study on third party servicing

- Timing & Outreach
  - Expect floor votes in late June/early July
    - Urge members to ignore Administration’s call to double user fees
    - Swiftly pass User Fee Package as negotiated
Breakthrough Pathway

• Establish accelerated transitional coverage for new med tech which FDA has designated as “breakthrough”
  – Current pathway takes 3 years

• Breakthrough must meet following conditions:
  – Provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
  – Has no approved alternatives
  – Offers significant advantages over existing approved alternatives
  – Availability is in the best interest of patients.

• SMTA Sign-on Letter
  – BioFlorida one of 32 associations to support