Highlights of the Cures Act's expanded access/compassionate use requirements include:

- A manufacturer or distributor of an investigational drug must make "public and readily available" its policies on evaluating requests for expanded access, such as by "posting such policies on a publicly available Internet website."
- The policies must include:
    - Contact information for the manufacturer or distributor to facilitate communication about expanded access requests;
    - Procedures for making such requests;
    - The general criteria used by the manufacturer or distributor to evaluate such requests for individual patients, and how the manufacturer or distributor responds to such requests;
    - The length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests; and
    - A hyperlink or other reference to the information on ClinicalTrials.gov for the clinical trials of the drug for which expanded access is sought.
- These updated requirements will apply to manufacturers or distributors of investigational drugs beginning the later of 60 days after enactment of the Cures Act (which will be February 11, 2017) or the "first initiation of a phase 2 or phase 3 study . . . with respect to such investigational drug."