

## ADVISORY REGARDING 30-DAY REQUIREMENT IN SECTION 1.03-5

Current State of Maine rules governing clinical drug trial results reporting require that a manufacturer report to the State when submissions of trial results to [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) are not posted within 30 days, if the time permitted for results posting for that trial has expired. See 10-144 Chapter 275, Department of Health and Human Services (or 26-239 Chapter 111, Office of Attorney General) §1.03-5.

This rule section reads:

In the case of posting to the publicly funded Internet website of the National Institutes of Health or its successor agencies, information shall be deemed to be posted on the date that information submitted by the manufacturer or labeler is accepted by the agency.

If the information has not appeared on such publicly funded website within thirty (30) days after submission to the agency so that the posting has not occurred within the time requirements of these rules, the manufacturer or labeler shall make written notification within the next thirty (30) days to the Department. This notice shall provide any information known to the manufacturer or labeler with respect to the specific date by which the information will appear, the reasons for the delay and the actions previously taken and to be taken in the future by the manufacturer or labeler to ensure posting on such publicly funded website. A manufacturer or labeler in compliance with this paragraph is exempted from the applicable time requirement insofar as it demonstrates that the cause of the delay is and remains solely the agency's or its website.

Although the Maine rule is consistent with federal statutory provisions, the State is aware of the practical time delays caused by the review of submissions for posting due to volume and complexity. Maine anticipates reevaluating this particular requirement in the rules.

In the meantime, the State informally advises the following approach:

If the information has not appeared on such publicly funded website within ninety (90) days after submission to the agency so that the posting has not occurred within the time requirements of these rules, the manufacturer or labeler shall make written notification within the next thirty (30) days to the Department unless such posting occurs in the interim.

Questions about this advisory may be directed to Thomas C. Bradley, Assistant Attorney General, State of Maine, through email at: [Thomas.bradley@maine.gov](mailto:Thomas.bradley@maine.gov) or by phone at 207-626-8813.