



May 21, 2026

**Re: Department of Public Health Regulation
105 CMR 272.000
*Standards Regulating the Care of Infants Identified as Being Affected by
Prenatal Substance Exposure***

The Massachusetts Medical Society (MMS) is a professional association of over 23,000 physicians, residents, and medical students across all clinical disciplines, organizations, and practice settings. The Medical Society is committed to advocating on behalf of patients, to give them a better health care system, and on behalf of physicians, to help them provide the best care possible.

The MMS strongly supported the Commonwealth's 2024 reforms to mandated reporting practices for infants affected by prenatal substance exposure (Chapter 285 of the Acts of 2024). These reforms represented a critical shift toward evidence-based and patient-centered approaches that promote engagement in prenatal care and treatment for substance use disorder (SUD). We commend the Department's efforts to operationalize this law and to promote standardized, supportive care for birthing people and infants. Accordingly, we appreciate the opportunity to provide comment on proposed regulation 105 CMR 272.000, *Standards Regulating the Care of Infants Identified as being Affected by Prenatal Substance Exposure*.

272.005: Definitions

The MMS is concerned that the proposed definitions of "Prenatal Substance Exposure" and "Prenatal Alcohol Exposure" are overly broad and may result in unintended consequences. As drafted, these definitions do not adequately distinguish between non-problematic use and clinically significant substance or alcohol use disorder. These definitions risk sweeping in low-risk patients, including those with isolated or historical use or those receiving appropriate medical treatment, thereby triggering unnecessary

clinical and administrative requirements. For example, individuals who disclose substance use prior to becoming aware of pregnancy, or those appropriately taking prescribed medications, including medications for opioid use disorder (MOUD) or medications used to treat conditions such as sickle cell disease, could be swept into the same category as patients with active substance use disorder. The MMS is also concerned that the proposed definitions may unintentionally encompass tobacco or nicotine use and rely too heavily on high-sensitivity screening tools or self-disclosure, which may identify patients as requiring intervention despite the absence of clinically significant substance use disorder.

The MMS recommends that the Department refine these definitions to incorporate clinically meaningful thresholds and clearer distinctions between screening results, exposure, and diagnosed substance or alcohol use disorder. Additional substance-specific guidance, particularly with respect to cannabis, would also improve clarity and consistency in application. Importantly, the appropriate use of prescribed medications should not, in and of itself, automatically trigger downstream requirements such as Family Care Plans.

272.015: Family Care Plan

Relatedly, the requirement that a Family Care Plan be developed in all cases of identified prenatal substance exposure is similarly overbroad and may not be clinically appropriate. While Family Care Plans are a valuable tool for coordinating care for patients with demonstrated need, their effectiveness depends on being tailored to individualized clinical and social circumstances and developed collaboratively with the birthing person on a voluntary basis. Requiring them universally risks diverting limited resources, increasing administrative burden on physicians and clinical staff, and introducing unnecessary intrusion into the lives of low-risk patients. The MMS therefore recommends that the regulation ensure that Family Care Plans are offered on a voluntary basis, rather than universally mandated, and targeted to patients with identified clinical needs.

Further clarification is also needed regarding the timing of plan development, ownership of the plan, and the scope of provider responsibility, including expectations related to the assessment of and referrals for other caregivers. Absent additional guidance, Family Care Plans may shift from patient-centered, family-owned care coordination tools to physician-driven compliance documents, potentially undermining their utility and increasing administrative burden without meaningful benefit to patients.

272.020: Data Collection & 272.030: Confidentiality of Data Provided to the Department

The MMS has concerns regarding the feasibility of the proposed data collection requirements. The proposed regulations do not provide sufficient clarity regarding the specific data elements that will be required, the reporting platform to be utilized, or the process through which reporting must occur. These details are critical to understanding the operational impact of the regulation. In addition, the requirement to report data prior to the birthing person's discharge does not align with existing clinical workflows. This approach could lead to delays in discharge for patients and increased administrative burden for physicians and clinical staff, particularly in cases where patients deliver outside of the health system in which they received prenatal care and complete records may not be readily available. We therefore recommend that the Department explicitly allow for monthly bulk data uploads and provide additional clarity regarding required data elements, reporting platforms, and submission processes.

Additionally, the requirement to provide individually identifiable data raises concerns regarding patient privacy and the potential impact on patient-provider trust. The MMS urges the Department to prioritize de-identified data whenever possible and, if identifiable data is required, to provide clear guidance on patient consent, disclosure, and communication.

Finally, the MMS also notes that the proposed regulations do not fully address the scope and operational impact of the expanded data collection requirements on attending physicians/clinicians. The reporting obligations appear to be significantly more detailed

and comprehensive than prior reporting to the Department of Children and Families and extend to patients without a diagnosis of substance use disorder or alcohol use disorder, including those with sub-clinical or non-problematic use. This expansion raises concerns about the volume of additional data that physicians and clinicians will be expected to collect, document, and report, as well as the lack of clarity regarding how this information is to be gathered within existing clinical workflows.

Absent further guidance and appropriate infrastructure, these requirements may place substantial administrative burden on physicians, disrupt care delivery, and hinder the timely submission of accurate data. Physicians have also expressed concern that overly expansive requirements may discourage routine screening conversations or documentation practices out of concern that low-risk patients will become subject to unnecessary reporting or intervention requirements. The MMS encourages the Department to more clearly define the scope of required data elements, assess the impact on clinical workflow, and ensure that reporting expectations are feasible within current care delivery systems.

The MMS remains committed to working collaboratively with the Department to support policies that advance evidence-based care, health equity, and the well-being of infants and families across the Commonwealth. Thank you for your consideration of these comments. For any questions, please contact Leda Anderson, Director of Advocacy & Government Relations, at Landerson@mms.org.