Taa R. Grays, Esq.
NYSBA, President
1 Elk Street
Albany, NY 12207
(917) 230-7336
tgrays@nysba.org

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Attention: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower, Empire State Plaza, Rm. 2438
Albany, New York 12237-0031
(via electronic mail: regsqna@health.ny.gov)

Re: Comments on Proposed Part 1008: Medical Aid in Dying

Dear Ms. Ceroalo,

The New York State Bar Association (hereinafter "NYSBA") respectfully submits these comments on the New York State Department of Health's (hereinafter "the Department") proposed regulations implementing physician-reporting requirements under Article 28-F of the Public Health Law. [1] These comments draw upon the *Report and Recommendations of the New York State Bar Association Task Force on Medical Aid in Dying* (hereinafter "the report"), drafted by experts with knowledge in multiple areas, including disabilities rights; elder law; health and public health law; insurance law; palliative care, hospice, and end-of-life care and approved by the NYSBA House of Delegates in January of 2024.

NYSBA supports the Department's effort to establish an effective reporting system before Article 28-F takes effect. While the proposal provides an appropriate foundation, it does not address some of the implementation issues identified in NYSBA's report. In particular, the regulations should more fully address ethics review, advance notification and external oversight for certain vulnerable or institutionally situated populations, clinical guidance concerning medication regimens, hospice capacity and state investment, and follow-up reporting after a prescription has been issued.

Ethics Review Committees

The proposed regulations do not address ethics review or require the attending physician to report whether an ethics committee was consulted. A general attestation that the attending physician, consulting

[1] *Medical Aid in Dying (MAID) Physician Reporting Requirements*, 48 N.Y. Reg. 20 (proposed June 3, 2026, to be codified at 10 N.Y.C.R.R. § 35.7 and pt. 1008)

physician, and mental health professional complied with Article 28-F does not indicate whether a material ethical or procedural conflict arose or how that conflict was resolved. [2]

The report recognized that ethics review committees can provide an important safeguard in difficult cases involving medical aid in dying. In discussing New York's existing safeguard framework under the Family Health Care Decisions Act, the report observed that ethics review committees may be particularly useful where questions remain concerning a patient's decision-making capacity or where the patient is isolated and lacks family, close friends, or other support. The report also recommended that the Department support the development and drafting of "*Ethics Review Committee Best Practices*" to assist in this compliance. [3] The report made a more specific recommendation concerning nursing homes and other residential or long-term-care institutions: nursing home ethics committees should review eligible residents' requests for medical aid in dying to ensure that the legally required process has been followed.[4]

To effectuate the recommendations noted by our Task Force, the Department should consider establishing a narrowly tailored and expedited ethics-review process. Except where the NYSBA report expressly recommends review of requests made by eligible nursing home residents, ethics review should not be required indiscriminately in every case and should occur only when a material and unresolved issue arises concerning voluntariness, coercion, compliance with Article 28-F, conflicting professional assessments, institutional policies, or the rights of an isolated or institutionally situated patient.

An ethics review committee should not function as an additional capacity evaluator, substitute its judgment for that of a patient with decision-making capacity, or possess authority to approve or disapprove the patient's request. Nor should ethics review introduce surrogate decision-making into a process that may be initiated only by the patient. The committee's role should be limited to reviewing legal and procedural compliance, assisting in the resolution of an identified conflict, and ensuring that the patient's rights are protected.

The Department should issue model procedures and best practices addressing the circumstances that warrant referral, committee composition, confidentiality, documentation, expedited review, and the committee's limited advisory or compliance review function. The process should not require family notification or participation and should not operate as an additional waiting period or unnecessary barrier to lawful access.

Section 1008.1(b) should also require the attending physician to report whether the matter was referred to an ethics review committee, the general reason for the referral, the date the review was completed, and whether any issue concerning compliance with Article 28-F remained unresolved. The substance of confidential committee deliberations should not be disclosed.

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[2] Medical Aid in Dying Physician Reporting Requirements, 48 N.Y. Reg. at 20 (proposed 10 N.Y.C.R.R. § 1008.1(b)(7)) at 2.
[3] NYSBA MAID Report at 11.
[4] *Id*. at 32.

Advance Notification and External Oversight for Special Populations

The report also recognized that the generally applicable safeguards contained in the Medical Aid in Dying Act may require additional structural support where a requesting patient is subject to institutional control, structural coercion, social isolation, or the oversight of a state service system. The report called for greater specificity through regulations and implementation oversight and recommended advance notification to existing entities capable of performing an external protective or oversight function. [5]

Specifically, the report recommended that:

1. When a person with an intellectual or mental health disability who is eligible for representation by the Mental Hygiene Legal Service requests medical aid in dying, adequate advance notification should be provided to MHLS. If the person is eligible for services through the Office for People with Developmental Disabilities or the Office of Mental Health, similar notification should be provided to the applicable agency.[6]
2. When a person residing in a nursing home or another residential or long-term-care institution requests medical aid in dying, adequate advance notification should be provided to the New York State Office of the Long-Term Care Ombudsman.[7]
3. When a person in a carceral setting requests medical aid in dying, adequate advance notification should be provided to Prisoners' Legal Services of New York because of the structural coercion inherent to incarceration.[8]
4. When a noncitizen held in a state jail or prison under an Immigration and Customs Enforcement detainer agreement requests medical aid in dying, adequate advance notification should be provided to Prisoners' Legal Services and NYC Health + Hospitals/Correctional Health Services.[9]

These recommendations do not contemplate that the notified entity would make the request on behalf of the patient, substitute its judgment for that of the patient, or possess a veto over the patient's decision. Advance notification is intended to activate the entity's existing protective, representational, or oversight function so that potential concerns involving coercion, voluntariness, communication barriers, access to independent advice, disability accommodations, institutional pressure, or procedural compliance can be identified before the prescription is issued.

The proposed regulations require the attending physician to report the patient's care setting but do not require the physician to identify whether the patient is eligible for representation, services, or oversight by one of these entities. Nor do the regulations require advance notification or documentation that notification occurred. [10]

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[5] NYSBA MAID Report supra note 2 at 32.
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Medical Aid in Dying Physician Reporting Requirements*, 48 N.Y. Reg. at 20 (proposed 10 N.Y.C.R.R. § 1008.1(b)(7)). At 2.

The Department should consider coordinating with MHLS, OPWDD, OMH, the Office of the Long-Term Care Ombudsman, correctional health authorities, Prisoners' Legal Services, and other appropriate entities to establish an advance-notification and external-oversight protocol before Article 28-F is implemented.[11]

The protocol should identify:

- the patients and settings for which notification is required;
- the person responsible for providing notice;
- the point in the process at which notice must be provided;
- the information that may be disclosed, consistent with patient consent and applicable confidentiality requirements;
- designated contacts and expedited response procedures within each entity;
- the scope of the entity's review, representation, or assistance;
- the documentation necessary to establish that notice was provided; and
- protections against unnecessary delay, obstruction, or interference with the decision of an eligible patient.

The notified entity should be permitted, consistent with its existing authority, to determine whether the patient has access to independent advice or representation; whether interpretation, communication assistance, or disability accommodations are needed; whether the request appears voluntary and free from institutional coercion; and whether the procedural requirements of Article 28-F have been followed.

The physician-reporting form should ask whether the patient was residing in an institutional or carceral setting or was eligible for services, representation, or oversight by a designated entity; whether advance notification was required; the entity notified; and the date notice was provided.

If the Department determines that all aspects of these recommendations cannot be implemented through Part 1008, it should issue coordinated guidance, enter into appropriate interagency agreements, or undertake additional rulemaking. The limited scope of this physician-reporting rule should not result in the absence of an operational protocol for populations expressly addressed in NYSBA's report.

Hospice and Palliative-Care Capacity

The implementation of Article 28-F should not occur in isolation from the State's responsibility to ensure meaningful access to high-quality hospice and palliative care. As recognized in the report, patients considering medical aid in dying should have meaningful access to appropriate end-of-life care, supported by adequately trained professionals and effective clinical infrastructure. [12] The Department should therefore work with hospice and palliative-care providers and other relevant stakeholders to assess workforce and infrastructure needs and identify appropriate state support as Article 28-F is implemented. Strengthening that system is both a fiscal and a moral imperative: medical aid in dying should supplement,

[11] NYSBA MAID Report at 32.
[12] *Id.* at 36-38

and never become a substitute for, accessible symptom management, hospice services, caregiver support, and other appropriate end-of-life care.[13]

Medication Regimens and Clinical Guidance

The proposed regulations require the attending physician to report the names of the medications prescribed, their strengths, and their dosage forms. They do not, however, provide clinical guidance concerning the combinations used for medical aid in dying or establish a mechanism for evaluating the performance of those regimens. [14]

The NYSBA Report discussed medication combinations used in Oregon, which has the longest period of reported experience with medical aid in dying, noting that in 2022, 70 percent of reported ingestions involved DDMAPH, a combination of diazepam, digoxin, morphine sulfate, amitriptyline, and phenobarbital. DDMAPH had a reported median time to death of 42 minutes. Twenty-eight percent of reported ingestions involved DDMA, consisting of diazepam, digoxin, morphine sulfate, and amitriptyline, with a reported median time to death of 49 minutes. The Report also noted that these combinations had longer median times to death than secobarbital and pentobarbital, which were no longer readily available. [15]

The Report does not recommend that New York codify one mandatory medication combination. A fixed regimen in regulation could become outdated as clinical evidence, medication availability, and standards of practice change. The Report does, however, emphasize the need for clinical training and practical guidance. It recommends a multidisciplinary approach to training and identifies practice guidelines, mentorship, simulations, and role-playing exercises as possible training methods. [16]

The Report specifically recommends that physicians who provide medical aid in dying prescriptions receive additional required training covering patient selection, medical-record requirements, medications used, legal administration of medications, and ongoing communication with patients and families. It also recommends continuing education, facility-based training, educational resources, training through palliative-care providers and professional organizations, expanded training through medical schools and residency programs, and a New York hotline to answer providers' medical and legal questions. [17]

To effectuate this, the Department should consider, in consultation with physicians, pharmacists, hospice and palliative care practitioners, and other professionals with relevant experience, develop and periodically update evidence based clinical guidance concerning appropriate medication regimens. The

[13] *Id.* at 12, 33-39.
[14] *Medical Aid in Dying Physician Reporting Requirements*, 48 N.Y. Reg. at 20 (proposed 10 N.Y.C.R.R. § 1008.1(b)(7)) at 1-2.
[15] NYSBA MAID Report at 23-24.
[16] *Id*. at 38-39.
[17] *Id.* at 39.

guidance should address medication selection, contraindications, preparation, administration, patient counseling, management of foreseeable complications, and the safe disposal of unused medication.

The guidance should be incorporated into the training made available to participating physicians and other health professionals. The Department should also establish or designate a resource through which practitioners may obtain timely medical, pharmaceutical, and legal guidance concerning implementation of Article 28-F, consistent with the Report's recommendation for a provider hotline. [18]

Follow-Up Reporting

The proposed regulations limit mandatory reporting to information available within five days after the prescription is issued. The *Regulatory Impact Statement* explains that the Department determined that the attending physician should report the information available at the time the physician prescribes the medication. [19]

That approach does not provide sufficient information to determine actual utilization. A prescription may never be filled, and a patient who obtains medication may decide not to use it. The Report's discussion of Oregon data distinguishes between prescriptions issued and medication ingested. It notes that, since Oregon's law took effect, 3,712 people had received prescriptions but 2,454, or 66 percent, had died after ingesting the medication. In 2022, 431 people received prescriptions while 278 ingested the medication.[20]

NYSBA therefore recommends a two-stage reporting system. The attending physician should submit the initial report after issuing the prescription, as the proposed regulations require. A supplemental report should then be submitted after the physician learns that the patient has died, self-administered the medication, decided not to use it, or otherwise concluded the medical aid in dying process.

The supplemental report should state, to the extent know nnd without an affirmative continuing duty to investigate:

- whether the prescription was filled;
- whether the patient self-administered the medication;
- the medications and dosages self-administered;
- the date and setting of self-administration;
- the approximate period between self-administration and death;
- whether a significant complication, unexpected outcome, or medical intervention occurred;
- whether unused medication remained;
- if known, how unused medication was disposed of

[18] *Id.*
[19] *Medical Aid in Dying Physician Reporting Requirements*, 48 N.Y. Reg. at 20 (proposed 10 N.Y.C.R.R. § 1008.1(b)(7)), Regulatory Impact Statement at 8, 9.
[20] NYSBA MAID Report at 23.

The Department should aggregate and publish this information in a manner that protects the identities and confidentiality of patients, families, practitioners, and institutions. Follow up reporting would allow the Department to distinguish prescriptions issued from medication used, assess utilization more accurately, evaluate medication regimens, identify unexpected outcomes, improve clinical guidance and training, and determine compliance with Article 28-F.

Conclusion

NYSBA respectfully recommends that the Department revise the proposed regulations or issue accompanying implementation guidance to establish an expedited and appropriately limited ethics review process for cases involving material unresolved issues and require nursing home ethics committee review of eligible residents' requests; [21] establish advance notification and external oversight protocols for the vulnerable and institutionally situated populations; [22] develop evidence based and periodically updated clinical guidance and training concerning medications used for medical aid in dying; [23] and require confidential follow up reporting sufficient to distinguish prescriptions issued from medications actually used and to evaluate utilization, outcomes, and compliance.

These additions would preserve patient autonomy while providing the structural safeguards, professional guidance, and meaningful data collection necessary for the responsible implementation of medical aid in dying in New York.

NYSBA thanks Mary Beth Morrissey Esq., PhD, MPH, and Mark Ustin, Esq., former Chairs of NYSBA's Health Law Section and members of the Medical Aid in Dying Task Force, for their assistance in drafting this comment.

If you have questions or need additional information, please contact me or NYSBA's Director of Government Relations, Matthew Pennello, at mpennello@nysba.org or via telephone at (518) 487-5748.

Respectfully,

Taa R. Grays
President

[21] *Id*. at 11 and 32.
[22] *Id.* at 32.
[23] *Id.* at 23-24; 38-39.