SUMMARY OF EXPRESS TERMS

A new section for Part 415 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is proposed, to be designated as section 415.41 and entitled "Specialized Programs for Residents with Neurodegenerative Diseases".

(a) General. For purposes of the proposed regulation, "Neurodegenerative Disease" shall mean Huntington's disease or Amyotrophic Lateral Sclerosis. "Specialized program" means a discrete unit within a nursing home that offers services and facilities for individuals with Neurodegenerative Diseases, with the goal of helping them attain or maintain the highest practicable level of physical, affective, behavioral and cognitive functioning. The program must be located in a nursing unit which is specifically designated for this purpose and physically separate from other facility units.

The proposed regulation also provides that the facility shall make information and data available to assist the Department of Health (department) in evaluating the effectiveness of specialty units and their impact on outcomes for individuals with Neurodegenerative Diseases.

(b) Admission. The proposed regulation requires nursing homes to develop written admission criteria for specialty units for individuals with Neurodegenerative Diseases. At a minimum, the resident's medical record must document that the resident has a

Neurodegenerative Disease diagnosis, cannot appropriately be served and is not safe in a less restrictive setting, and can benefit from the care and services available in a specialty unit. The proposed regulation also provides that a facility shall evaluate the effects of its admission criteria on its success in achieving its goals and objectives for the specialty unit and requires the facility to report its findings to the department annually thereafter.

(c) Assessment and Care Planning. The proposed regulation requires a home evaluation with the future resident and his or her family, as appropriate, prior to admission to discuss care needs. The proposed regulation also requires development of a care plan for each resident, which shall include a discharge plan, by an interdisciplinary resident care team. The care plan must be reviewed and modified at least once a month for the first three months following admission and then quarterly or upon a significant change in the resident's condition thereafter.

(d) Discharge. The proposed regulation requires that a proposed discharge plan must be developed within 30 days of admission for each resident as part of the overall care plan and shall include input from all professionals caring for the resident, the resident and his or her family, as appropriate, and any outside agency or resource anticipated to be involved with the resident following discharge. The resident must be discharged to a less restrictive setting when he or she no longer meets one or more of the admission criteria for the unit. Additionally, the proposed regulation provides that a facility shall evaluate the effects of its discharge criteria on its success in achieving the goals and objectives for the specialty unit and requires the facility to report its findings to the department annually

thereafter.

Nursing homes with specialty units shall have a written agreement with a general hospital or hospitals providing for the transfer of residents in need of emergency or acute inpatient care services. Such hospital(s) shall have expertise in caring for individuals with Neurodegenerative Diseases, except in cases where a general hospital with such expertise is not available within a distance and time considered reasonable by accepted emergency medical standards. In the event of a transfer to any general hospital, the facility must require a member of the specialty unit's staff to accompany the resident, if feasible, and must communicate with the hospital and provide any relevant information about the resident at the time of transfer. The resident shall be given priority readmission status to the unit as warranted by his or her condition.

(e) Program/Unit Staffing Requirements. The facility must maintain consistent assignment of direct care staff to residents in the specialty unit. In addition, the proposed regulation requires that a specialty unit shall be managed by a program coordinator and that a physician must be responsible for medical direction of the unit. The proposed regulation also identifies other specific categories of personnel who must be assigned or available to the specialty unit, including a psychiatrist, a clinical psychologist or licensed clinical social worker, at least one registered professional nurse on each shift, a respiratory therapist, and a therapeutic recreation specialist.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health in section 2803(2) of the Public Health Law, Part 415 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended by adding a new section 415.41 to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

415.41 Specialized Programs for Residents with Neurodegenerative Diseases.

(a) General.

1 . " Specialized program" shall mean a discrete unit with a planned array of services, staffing, equipment and physical facilities designed to serve individuals with Neurodegenerative Diseases, and approved pursuant to Part 710 of this Title. The program shall provide goal-directed, comprehensive and interdisciplinary services directed at attaining or maintaining the individual at his or her highest practicable level of physical, affective, behavioral, psychosocial and cognitive functioning.

2. For purposes of this section, "Neurodegenerative Disease" shall mean Huntington's disease or Amyotrophic Lateral Sclerosis.

3. For purposes of this section, and consistent with the requirements of section 415.11 of this Part, the program shall have an "interdisciplinary resident care team" consisting of, at a minimum, the resident's physician, a registered professional nurse with responsibility for the resident and, depending on the resident's diagnosis, needs and symptoms, other appropriate staff in disciplines determined to meet the resident's needs which may

include staff assigned to the unit as set forth in subdivision (e) of this section.

4. The program shall be located in a nursing unit which is specifically designated for this purpose and physically separate from other facility units. Residents of the unit shall have access to all of the facility's recreational and therapeutic resources, including those resources that are not located in the unit.

5. The facility shall ensure that sufficient space, equipment and facilities are available to support the clinical, education and administrative functions of the program in accordance with the standards set forth in Parts 711 and 713 of this Title.

6. In addition to the implementation of the quality assessment and assurance plan for this program as required by section 415.27 of this Part, the facility shall participate with the department in an evaluation of the efficacy and effectiveness of the program and its impact on residents, families and staff. The facility shall collect data and furnish records, reports and data in a format requested by the department and shall make members of the interdisciplinary resident care team available for participation in the evaluation, as requested by the department. The facility shall submit such information to the department for the period ending December 31, no later than ninety days following the end of the calendar year, annually through calendar year 2021.

7. This section shall be implemented as a Quality Assessment and Performance Improvement (QAPI) project, as described in guidance from the federal Centers for Medicare and Medicaid Services.

(b) Admission.

1. The facility shall develop written admission criteria for the specialty unit to include the criteria in paragraph (2) of this subdivision and take into account the facility's goals and objectives regarding outcomes (e.g. minimizing self-inflicted injuries/falls, chorea-related trauma, hospitalization (length of stay), emergency department utilization, bed hold, and satisfaction surveys of residents with Neurodegenerative Diseases staff, families, and others) for residents who live in the specialty unit. The facility shall evaluate the effects of its admission criteria on its success in achieving its goals and objectives for the unit and report its findings to the department no later than ninety days following the end of the calendar year, annually through calendar year 2021.

2. At a minimum, for residents admitted to the unit, there shall be documented evidence in the resident's medical record that:

(i) the resident has been diagnosed with Neurodegenerative Disease based on a medical evaluation by a physician as determined by highly suggestive family history, neurological testing, genetic testing when available, formal consultation setting and/or formal neurological diagnostic consultation.

(ii) the resident cannot be managed and is not safe, and his or her needs cannot be met, in an available, less restrictive setting; and

(iii) the resident has the ability to benefit from the specialized care and services available in the unit.

(c) Assessment and Care Planning.

1. Any assessment of a potential resident must include the admission criteria described in paragraph (2) of subdivision (b). Where feasible, one or more members of the staff of the specialty unit shall conduct an evaluation of the home or current residence, living situation or inpatient setting of the future resident and his or her family prior to admission to discuss care needs. For purposes of this paragraph, "feasible" means the resident's home or other setting is within reasonable travel distance (in terms of round trip travel time) from either the facility or the home(s) of the staff member(s) conducting the home evaluation. Results of an evaluation shall be used to identify preliminary approaches and interventions appropriate for the resident for purpose of preparing a resident's care plan.

2. A care plan shall be prepared by the interdisciplinary resident care team for each resident, taking into account input from the resident and the resident's family or caregivers, in conformance with the timeframes set forth in section 415.11 of this Part. Each resident's care plan shall include care and services that are therapeutically beneficial to the resident, appropriate to the resident's interests and selected by the resident or resident's caregiver as appropriate. The care plan may require environmental accommodations, as well as results from any evaluation of the home or current residence, living situation, or inpatient setting of the resident.

3. Based on the resident's response to therapeutic interventions, as well as the progression of the disease and its impact on the resident's functioning, health and psychosocial status, the resident shall be reassessed and the care plan, including the discharge plan described in the next subsection hereof, shall be reviewed and modified at least once a month for the first three months following admission and then quarterly or upon any significant change in the resident's condition thereafter. The care plan shall be reviewed by at least three members of the interdisciplinary resident care team and shall include at least one certified nurse aide who is assigned to the resident on a permanent basis.

4. Facility or unit staff shall initiate a discussion of advance directives in accordance with the provisions of section 400.21 of this Subchapter with the resident and the resident's family member or other adult, consistent with such section, as soon as practicable following the decision to admit the resident to the unit.

(d) Discharge.

1. The facility shall develop written discharge criteria for the specialty unit, which at a minimum shall address the provisions of paragraph (5) of this subdivision.

2. The resident and his or her family and caregivers shall be notified of discharge criteria upon admission.

3. A written discharge plan shall be developed within 30 days of admission for each resident as part of the overall care plan and shall include input from all professionals

caring for the resident, the resident's family and caregivers, as appropriate, and any outside agency or resource anticipated to be involved with the resident following discharge. The discharge plan shall be reviewed and modified at least once a month for the first three months following admission and then quarterly or upon any significant change in the resident's condition thereafter.

4. When the interdisciplinary resident care team determines that discharge of a resident to another facility or community-based program is appropriate, a discharge plan shall be implemented which is designed to assist and support the resident, family and caregivers in the transition to the new setting. The resident, his or her family, and caregivers, as appropriate, shall receive preparation for discharge from the specialty unit through the facility's educational and counseling services.

5. The resident shall be discharged to a less restrictive setting when he or she no longer meets the minimum admission criteria for the unit set forth in paragraph (2) of subdivision (b) of this section or meets other discharge criteria established pursuant to paragraph (1) of this subdivision.

6. The facility shall evaluate the effects of its discharge criteria on its success in achieving its goals and objectives for the unit and report its findings to the department no later than ninety days following the end of the calendar year, annually through calendar year 2021.

7. (i) The facility shall have a written agreement with a general hospital or hospitals providing for the transfer of residents in need of emergency or acute inpatient care services. Such hospital(s) shall have expertise in caring for individuals with Neurodegenerative Diseases, except in cases where a general hospital with such expertise is not available within a distance and time considered reasonable by accepted emergency medical standards.

(ii) In the event a resident of a specialty unit requires transfer to a general hospital:

(a) When feasible and practicable, a resident who is transferred to a hospital shall be accompanied by an informed member of the program's direct care staff to ensure continuity of care. For purposes of this paragraph, "feasible" means that round trip travel time between the facility and the hospital is reasonable.

(b) When it is not feasible for a staff member to accompany the resident to the hospital, the resident's physician, or the specialty unit's medical director, or their designee, shall communicate with a physician or another health care practitioner at the receiving hospital at the time of the transfer.

(c) In either case, the staff member or physician shall provide to the receiving hospital appropriate documentation and other information that may be needed at the time of transfer to ensure continuity of care.

(d) The resident shall be given priority readmission status to the unit as his or her condition may warrant.

(e) All transfers shall be conducted in compliance with all other applicable law, including without limitation, section 415.3(h) of this Title.

(e) Program/Unit Staffing Requirements.

1. The facility shall maintain a level of direct care staff to residents that is appropriate for the required degree of care for the residents in the program unit.

2. The facility shall ensure that any direct care staff assigned to the unit have been thoroughly trained and educated with regard to the special needs of unit residents, are competent to work in the unit, and are familiar to unit residents.

3. The assignment of direct care staff must be sufficient to enable timely and appropriate care as determined by resident assessment and to protect both resident and staff safety. In addition to the staff assigned to the unit as specified in this subdivision, the facility shall make available other staff as necessary for the provision of care and services set forth in each resident's care plan.

4. The unit shall be managed by a program coordinator who has formal education, training and experience in the administration of a program that focuses on the care and

management of individuals with Neurodegenerative Diseases. The program coordinator shall be dedicated only to the specialty unit. The program coordinator shall be responsible for the operation and oversight of the program. Other responsibilities of the program coordinator shall include:

(i) planning for and coordination of direct care and services;

(ii) screening prospective admissions;

(iii) developing and implementing in-service and continuing education programs, in collaboration with the interdisciplinary resident care team, for all staff in contact or working with these residents;

(iv) participating in the facility's decisions regarding resident care and services that affect the operation of the unit; and

(v) ensuring the development and implementation of a program plan and policies and procedures specific to this program.

5. A physician who preferably has specialized training in the care of individuals with Neurodegenerative Diseases shall be responsible for the medical direction and medical oversight of this program and shall assist with the development and evaluation of policies and procedures governing the provision of medical services in this unit. If, at the time the

physician is appointed as medical director of the unit, he or she does not have experience in providing care to individuals with Neurodegenerative Diseases, he or she shall have access to physicians who do have such experience.

6. A psychiatrist shall be available on staff or on a consulting basis (including via telemedicine in conformance with applicable law) to the residents and to the program at a level consistent with residents' care plans. The facility shall exercise best efforts to utilize a psychiatrist who has clinical experience working with individuals who have Neurodegenerative Diseases.

7. A clinical psychologist or a licensed clinical social worker shall be available on staff or on a consulting basis (including via telemedicine in conformance with applicable law) to staff, residents, and residents' family members and caregivers at a level consistent with residents' care plans. The facility shall exercise best efforts to utilize a clinical psychologist or a licensed clinical social worker who has clinical experience working with individuals who have Neurodegenerative Diseases.

8. A social worker shall be available either on staff or on a consulting basis to work with the residents, staff and family as needed. The facility shall exercise best efforts to utilize a social worker who has experience working with individuals who have Neurodegenerative Diseases.

9. There shall be at least one registered professional nurse deployed on each shift in the

unit. The facility shall exercise best efforts to utilize registered professional nurses who have training and experience in caring for individuals with Neurodegenerative Diseases. This registered professional nurse may not be the specialty unit program coordinator required under paragraph (4) of this subdivision.

10. A therapeutic recreation specialist certified by a nationally recognized body which is acceptable to the department shall be responsible for the therapeutic recreation program.

11. A respiratory therapist shall be available to residents who are no longer able to maintain normal oxygen and carbon dioxide levels.

(f) Program/Unit Service and Environmental Requirements.

1. The program shall consist of a variety of medical, behavioral, counseling, recreational, exercise, nutritional and other services appropriate to the needs of each individual resident.

2. Specific services that shall be available to residents who need them include but are not limited to: neurology; pulmonary specialist; psychotherapy; physical, occupational, respiratory and speech therapy; specialized eating and nutritional interventions to maximize independence and prevent unplanned weight loss and dehydration; technology to enable the resident to communicate effectively with staff, family members, caregivers, friends, and other residents; and oral care. Consults as needed shall be provided by but are not limited to surgical, podiatry, optometry, ophthalmology, orthopedic, cardiac,

gastroenterology, dental, and hearing licensed professionals.

3. The therapeutic recreation program shall incorporate the principles of rehabilitation, occupational, physical, nutritional, and speech therapies.

4. Appropriate activities that accommodate individual residents' interests shall be available at times that accommodate their waking hours.

5. Support groups for staff, residents, and residents' family members and caregivers shall be established and facilitated by the social worker or other counseling professional.

6. The environment shall be customized to meet the needs and characteristics of residents and minimize injuries to residents and staff.

(i) Each resident's living space shall be customized to safely accommodate his or her specific movement and motor control characteristics, and changes in movement and motor control characteristics as the resident's disease evolves.

(ii) Such customization may include, but is not limited to, padding around hard surfaces that could harm the resident, staff or visitors; self-protective equipment such as soft helmet, elbow and knee pads; broda chairs (including shower/commode, bariatric, geriatric and glider chairs) with HD special padding if needed; and adequate space to accommodate high amplitude involuntary movements without injury to either the resident,

staff or visitors.

(iii) The unit shall include, in their new construction designs, small recreational and dining room areas where residents can be with their families in privacy and comfort.

(iv) Units shall include central bathing and toilet facilities that can accommodate two-person assists. In-room toilets and bathing accommodations shall be modified or restricted to ensure resident safety and privacy as described in (i) and (ii).

7. The unit shall be equipped and staff shall be trained as necessary for the provision and management of non-invasive ventilation for residents for whom this service is appropriate. Supervision shall be provided by a respiratory therapist and pulmonary specialist.

8. Residents shall not be prevented from participating in research projects and clinical trials that have been approved by an Institutional Review Board (IRB) that is registered with the federal Office of Human Research Protection (OHRP) in the United States department of Health and Human Services and in compliance with the human subjects research requirements at 45 CFR Part 46 as determined by OHRP. To the extent practicable, facilities may facilitate residents' participation in such research and trials by, for example, becoming trial sites, providing transportation to the trial site, providing assistance to enroll in the research, and working with families to facilitate participation.

9. The facility shall provide outdoor access to residents.

(g) Program/Unit Training Requirements

1. The facility shall ensure that all staff assigned to the direct care of the residents have pertinent experience or have received training in the care and management of people with Neurodegenerative Diseases.

2. Training shall be appropriate to the functions and responsibilities of specific staff in the unit and shall include but not be limited to:

(i) the Neurodegenerative Disease itself, e.g., signs and symptoms, genetics, diagnosis, management, progression/history of the disease, prognosis and epidemiology;

(ii) how each type of staff can contribute to better quality of care and quality of life for residents;

(iii) injury prevention for the resident, staff and visitors;

(iv) creating an organized environment that minimizes stressors, maintains routines and encourages/maximizes independent functioning and decision-making;

(v) ensuring adequate hydration and nutrition; and

(vi) providing and encouraging cognitive stimulation and socialization through passive

and active participation in appropriate activities.

3. Families and informal supports, including the resident's friends and caregivers, shall also have access to this training as appropriate to their activities in the unit.

4. The facility shall ensure that educational programs are conducted for staff who do not provide direct care but who come in contact with the residents on a regular basis such as housekeeping and dietary aides. The educational programs shall familiarize staff with the goals of the specialty unit and the needs of residents with Neurodegenerative Diseases.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 2803(2)(v) provides that the Public Health and Health Planning Council shall adopt rules and regulations, subject to the approval of the Commissioner of Health, governing the standards and procedures followed by nursing homes which, at a minimum, must meet federal standards.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State through the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. The proposed amendments are consistent with this objective through the development of specialty units designed to address the unique needs of individuals with Neurodegenerative Disease and help them maintain or attain the highest practicable level of physical, affective, behavioral and cognitive functioning.

Needs and Benefits:

The purpose of the proposed amendments to 10 NYCRR Part 415 is to provide regulatory standards for nursing home specialty care units for people with Neurodegenerative Diseases. The environmental and care needs for nursing home residents with Neurodegenerative Diseases, at least before the end stages of the disease, often vary from those of other populations in need of nursing home care today. The proposed standards

do not codify clinical pathways and interventions as these may change over time. Rather, they describe the service and environmental needs of people with Neurodegenerative Diseases and the nursing home's responsibilities to meet the resident's needs as well as, to a certain extent, their families' needs.

Four nursing homes have taken steps to create specialty units for people with Neurodegenerative Diseases. Specifically, the following facilities either have already established specialized care units for people with Neurodegenerative Diseases or have submitted Certificate of Need (CON) applications to do so:

- Terence Cardinal Cooke Health Care Center – an established 48-bed unit in New York City;
- Ferncliff Nursing Home – an established 38-bed unit in Rhinebeck;
- Victoria Home – CON submitted for a 12-bed unit in Ossining; and
- Sitrin Health Care Center – CON submitted for a 32-bed unit in New Hartford.

These four facilities will serve as a statewide resource for individuals with Neurodegenerative Diseases, leading to better service for people living in New York and repatriation of out-of-state residents to nursing homes that are closer to their home communities and families. For example, there are currently about 50 Medicaid-eligible New Yorkers with Huntington's disease living in out-of-state nursing homes. Many of these New Yorkers would not have had to seek nursing home care outside of New York had there been a nursing home capable of caring for them closer to their home communities and families.

Costs to Regulated Parties:

Nursing homes are not required to implement the proposed regulation since the operation of specialty units is voluntary. A nursing home may incur costs associated with the construction of a specialty unit for individuals with Neurodegenerative Diseases. The department will establish Medicaid reimbursement rates for nursing home providers for delivering appropriate services through the specialty units. A facility is unlikely to apply for approval to operate a specialty unit if it does not expect that doing so will be cost effective.

Costs to Local Governments:

Nursing homes are not required to implement the proposed regulation, as the operation of specialty units is voluntary. To the extent a nursing home operated by a local government seeks approval to operate a specialty unit, the costs will be the same as for other regulated parties who operate such units.

Costs to State Government:

The proposed rule does not impose any new costs on state government, as regulation of specialty units will be managed as part of the department's overall nursing home surveillance activities.

Local Government Mandates:

The proposed amendments do not impose any program, mandate, service, duty or

responsibility upon any county, city, town, village, school district, fire district or other special district. Implementation is voluntary.

Paperwork:

Nursing homes interested in operating a specialty unit for individuals with Neurodegenerative Diseases would need to submit and receive approval of a CON application. In addition, nursing homes are already required to maintain compliance with certain reporting, record-keeping obligations and staffing under federal and State requirements. For nursing homes interested in providing specialty care for Neurodegenerative Diseases, which is voluntary, the proposed regulations require additional reporting on admissions, discharges and outcomes and compliance with certain staffing requirements as necessary to meet the objectives of the specialty units. This additional reporting will allow the department to assess compliance and implementation.

Duplication:

The proposed regulation does not duplicate, overlap or conflict with any other State or federal rules and regulations, but sets forth additional standards for care in specialty units for individuals with Neurodegenerative Diseases.

Alternatives:

"Scatter beds" as opposed to specialty unit beds were considered but rejected. Specialty units are preferable from a clinical perspective, as they will enable residents to be cared for by an interdisciplinary care team in a customized environment, and likely will be

more cost effective in providing residents with the enhanced level of service required.

Federal Standards:

The proposed amendments exceed federal standards by setting forth additional standards for care in specialty units for individuals with Neurodegenerative Diseases.

Compliance Schedule:

As implementation of the proposed amendments is voluntary, there is no compliance schedule. CON applicants will determine a compliance schedule in conformance with the scope of changes needed in their facilities to accommodate the specialty unit regulatory requirements.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

Implementation of this rule is voluntary, subject to submission and approval of a Certificate of Need (CON) application. It is not known how many small nursing homes (those with less than 100 beds), or how many nursing homes owned and operated by counties and cities, will choose to implement the proposed regulation.

Compliance Requirements:

Nursing homes are already required to maintain compliance with record-keeping obligations and staffing under federal and State requirements. For nursing homes interested in providing specialty care for Neurodegenerative Diseases, which is voluntary, the proposed regulations require additional reporting on admissions, discharges and outcomes and compliance with certain staffing requirements as necessary to meet the objectives of the specialty units. This additional reporting will allow the department to assess compliance and implementation.

Professional Services:

Implementation is voluntary. The professional staff needed to comply with the proposed specialty unit regulations do not vary from the professional staff required to comply with current nursing home rules and regulations, except that the proposed regulation expresses a preference for professional staff with experience in meeting the unique needs of individuals with Neurodegenerative Diseases.

Compliance Costs:

Implementation of the proposed regulation is voluntary, subject to submission and approval of a CON application. A nursing home may incur costs associated with the construction of a specialty unit for individuals with Neurodegenerative Diseases. The department will establish Medicaid reimbursement rates for nursing home providers for delivering appropriate services through the specialty units. A facility is unlikely to apply for approval to operate a specialty unit if it does not expect that doing so will be cost effective.

Economic and Technological Feasibility:

The proposed regulation is economically and technically feasible. In particular, implementation is voluntary, and a nursing home is unlikely to propose construction and operation of a specialty unit unless it is cost-effective for the facility.

Minimizing Adverse Impact:

As implementation of the proposed rule is voluntary, a nursing home is unlikely to propose construction and operation of a specialty unit unless it is cost-effective for the facility.

Small Business and Local Government Participation:

The department created a stakeholder advisory group, which helped guide the development of the proposed regulation. The members of this group include representatives of small businesses, nursing homes specifically interested in serving

individuals with Neurodegenerative Diseases, as well as family members and advocates for individuals with Neurodegenerative Diseases, and clinical experts with experience caring for such individuals. In addition, a copy of this notice of proposed rulemaking will be posted on the department's website. The notice will invite public comments on the proposal and include instructions for anyone interested in submitting comments, including small businesses and local governments.

The proposed regulation provides that the facility shall make information and data available to assist the department in evaluating the effectiveness of specialty units and their impact on outcomes for individuals with Neurodegenerative Diseases. Such evaluation will be conducted four years after the adoption of the proposed regulations and the department will consider whether changes are warranted to the programmatic requirements. This period of time is designed to ensure that there is sufficient experience to allow the department to assess implementation.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

While there are a number of nursing homes located in rural areas throughout the State, implementation of the proposed rule is voluntary. Nursing homes in rural areas will not be affected differently than those in non-rural areas.

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

Nursing homes are already required to maintain compliance with certain reporting, record-keeping obligations and staffing under federal and State requirements. For nursing homes interested in providing specialty care for Neurodegenerative Diseases, which is voluntary, the proposed regulations require additional reporting on admissions, discharges and outcomes and compliance with certain staffing requirements as necessary to meet the objectives of the specialty units. This additional reporting will allow the department to assess compliance and implementation.

Costs:

Implementation of the proposed rule is voluntary, subject to the submission and approval of a Certificate of Need application. A nursing home may incur costs associated with the construction of a specialty unit for individuals with Neurodegenerative Diseases. The department will establish Medicaid reimbursement rates for nursing home providers for delivering appropriate services through the specialty units. A facility is unlikely to apply

for approval to operate a specialty unit if it does not expect that doing so will be cost effective.

Minimizing Adverse Impact:

As implementation of the proposed rule is voluntary, a nursing home is unlikely to propose construction and operation of a specialty unit unless it is cost-effective for the facility.

Rural Area Participation:

The department created a stakeholder advisory group, which helped guide the development of the proposed regulation. The group's members are located throughout the state and include family members and advocates for individuals with Neurodegenerative Diseases, clinical experts with experience caring for individuals with Neurodegenerative Diseases, and representatives of nursing homes interested in serving such individuals. In addition, a copy of this notice of proposed rulemaking will be posted on the department's website. The notice will invite public comments on the proposal and include instructions for anyone interested in submitting comments, including individuals and entities located in rural areas.

The proposed regulation provides that the facility shall make information and data available to assist the department in evaluating the effectiveness of specialty units and their impact on outcomes for individuals with Neurodegenerative Diseases. Such evaluation will be conducted four years after the adoption of the proposed regulations and

the department will consider whether changes are warranted to the programmatic requirements. This period of time is designed to ensure that there is sufficient experience to allow the department to assess implementation.

STATEMENT IN LIEU OF
JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.