

Language Assistance and Official New York State Prescription Form Requirements

Effective date: 3/27/13

Pursuant to the authority vested in the Commissioner of Health by Section 281(2) of the Public Health Law, Section 910.2 of Title 10 of Part 910 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to add a new subdivisions (g) and (h), to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

(g) A section wherein prescribers may indicate whether an individual is limited English proficient, as defined in section sixty-eight hundred twenty-nine of the education law, shall be included on the Official New York State prescription form. A line shall also be provided on the form where the prescriber may specify the preferred language indicated by the patient in those cases where the patient is limited English proficient. Failure to include such indication on the part of the prescriber shall not invalidate the prescription.

(h) Any Official New York State prescription form that does not contain the limited English proficient section and preferred language line described in subdivision (g) may still be utilized by a prescriber if the form was received from the Department prior to March 30, 2013. For any Official New York State prescription form without the limited proficient section and preferred language line, the prescriber may indicate on the front of that Official New York State prescription form whether the patient is limited English proficient, and, if so, the prescriber shall also indicate the patient's preferred language.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 281(2) of the Public Health Law requires the Commissioner to promulgate regulations necessary to implement the provisions of Article 2-A of the Public Health Law in order to effectuate its purposes and intent with regard to patients having limited English proficiency. The Department proposes amendments to the regulations that would effectuate the necessary changes in that regard due to Chapter 447 of the Laws of 2012.

Legislative Objectives:

The legislative purpose of Section 281 of the Public Health Law, among other provisions, is to promote safe and effective use of prescription medications by reducing the barriers many consumers of limited English proficiency face in trying to understand prescription drug labels, dosage instructions and other vital patient information.

Needs and Benefits:

Language barriers and the inability to read or understand prescription information can pose health risks to patients with limited English proficiency. Amendments to Section 281 of the Public Health law require prescription forms and electronic prescriptions to include a section that allows prescribers to indicate whether an individual is limited English proficient and, if so, the preferred language of the patient. These individuals will benefit by lessened risk of adverse drug events, resulting in fewer visits to emergency departments, fewer hospitalizations and lessened risk of death. This amendment will support legislation passed under Chapter 447 of the Laws of 2012 that aims to reduce the number of medication errors by identifying patients of limited English proficiency so that they can be provided with competent interpretation services and thus avoid health risks associated with prescribed medications.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

The New York State Department of Health provides practitioners, authorized to issue prescriptions, with Official New York State prescription forms. These prescription forms will be modified to include a section or check box that will meet the requirement of indicating limited English proficiency, at no additional cost. A line will also be provided on these forms to allow for the specification of the preferred language, also at no cost to the State or the regulated parties. The proposed rule does not require the regulated entities to perform any additional tasks associated with format of the Official New York State prescription form; although they will be able to add such spaces to those existing forms which do not already have such lines. The new regulatory requirements are not anticipated to have a fiscal impact on authorized prescribers.

Costs to State and Local Government:

The proposed rule will not affect the cost of prescription forms provided to practitioners in New York State. Inclusion of the section to identify limited English proficiency and a line to include the preferred language will be at no cost to the Department of Health's Official Prescription Program.

Inclusion of subdivision (h), allowing practitioners to use and amend current stock would impose no costs to the Department. In addition, allowing prescribers to amend current Official New York State prescription forms avoids two distinct problems. First, it avoids the cost of replacing all Official New York State prescription forms, which are furnished by the Department, currently in the possession of prescribers and institutions. Second, by allowing prescribers and institutions to use current stock, there will be no need to remove Official New York State

prescription forms from current safeguarded locations for the purpose of returning them to the Department or have them destroyed in a safe and secure manner. The theft of Official New York State prescriptions forms is a continuing and costly problem facing the Department, prescribers, institutions, and law enforcement. Moving millions of Official New York State prescription forms from over 130,000 prescribers, in a manner that is outside the normal course of business, would invite theft of these forms on a wide scale.

Costs to the Department of Health:

The proposed rule will not affect the cost of prescription forms provided to practitioners in New York State. Inclusion of the section to identify limited English proficiency and a line to include the preferred language will be at no cost to the Department.

Local Government Mandates:

The proposed rule does not constitute a mandate on local government; nor does it impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other specific district.

Paperwork:

This regulation imposes no new reporting or filing requirements.

Duplication:

As this proposed regulatory amendment was developed in consultation with the Commissioner of Education, the requirements conform to those of the State Education Law and the State Education Commissioner's regulations. The requirements of this proposed regulation do not duplicate any other state or federal requirement.

Alternatives:

Amendment of the regulation is required by statute. There were no significant alternatives to be considered during the regulatory process.

Federal Standards:

The regulatory amendments do not exceed any minimum standards of the federal government.

Compliance Schedule:

Regulated parties should be able to comply with these regulations effective upon publication of a Notice of Adoption in the New York State Register.

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**REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL
GOVERNMENTS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

RURAL AREA FLEXIBILITY ANALYSIS

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse impact on entities in rural areas, and it does not impose reporting, record keeping or other compliance requirements on entities in rural areas. The proposed rule does not require the regulated entities to perform any additional tasks associated with format of the Official New York State prescription form; although they will be able to add such spaces to those existing forms which do not already have such lines. The provisions of this regulation apply uniformly throughout New York State.

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.

Assessment of Public Comment

Public comments were submitted to the NYS Department of Health (DOH) in response to this regulation.

The public comment period for this regulation ended on March 4, 2013. DOH received two comments.

These comments and DOH's responses are summarized below:

1. COMMENT: A comment received from Hinman Straub, P.C. indicated that proposed changes to the Official New York State Prescription form, under this proposed regulation, did not raise any concerns. Comments provided by Hinman Straub, P.C. were centered on the obligations of the dispensing pharmacy when a prescriber indicates that the patient is limited in English proficiency and the lack of any guidance or requirements in the proposed regulations for pharmacies to respond to a prescription indicating that the patient is limited in English proficiency.

RESPONSE: Concerns related to the requirements to respond to a prescription indicating a patient is limited in English proficiency are not addressed under this regulation but it is expected that these concerns will be addressed in regulations to be proposed by the State Education Department in compliance with Section 6829 of the Education Law.

2. COMMENT: One comment was on behalf of the SAFE Rx Coalition and was in support of the proposed changes to the Official New York State Prescription form.

Since both comments to this proposed regulation were supportive, no changes were made to the proposed regulation.