CA 23-00161

NYSCEF DOC. NO. 17

RECEIVED NYSCEF: 09/19/2023



STATE OF NEW YORK OFFICE OF THE ATTORNEY GENERAL

LETITIA JAMES ATTORNEY GENERAL

BARBARA D. UNDERWOOD SOLICITOR GENERAL DIVISION OF APPEALS & OPINIONS

September 19, 2023

Hon. Ann Dillon Flynn
Clerk of the Court
New York Supreme Court
Appellate Division – Fourth Department
M. Dolores Denman Courthouse
50 East Avenue, Suite 200
Rochester, New York 14604

Re: Med. Prof'ls for Informed Consent v. Bassett A.D. No. CA 23-00161

Dear Ms. Dillon Flynn,

I represent the appellants in the above-referenced matter, which was argued on May 24, 2023. In accordance with 22 N.Y.C.R.R. § 1000.15(e), appellants respectfully seek leave to offer the attached post-argument submission. Consistent with my statements at oral argument, at which I announced that the New York State Department of Health ("DOH") intended to repeal 10 N.Y.C.R.R. § 2.61, I am attaching (1) a Notice of Adoption of rules that includes the repeal of § 2.61, which DOH submitted to the Department of State on September 18, 2023, and (2) confirmation from the Department of State that it intends to publish adopted rules in the State Register on October 4, 2023. Upon publication in the State Register—at which point the repeal will be final—I will promptly notify the Court.

Respectfully submitted,

JONATHAN D. HITSOUS
Assistant Solicitor General

Via NYSCEF:

Sujata Sidhu Gibson, Esq., GIBSON LAW FIRM, PLLC Counsel for Respondents 120 E. Buffalo Street Suite 2 Ithaca, New York 14850 Attachment 1: Notice of Adoption

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<i>:</i>	
	For Department of State us
Notice of Adoption	Health, Department of (SUBMITTING AGENCY)
x] This adoption will amend the NYCRR.	
This adoption will not amend the NYCRR.	
forms will be cause for rejection of this notice. chang	this form. Please be sure to COMPLETE ALL ITEMS. Incomplete ge in text
 Action taken: Repeal of Section 2.61 from Title 10 NYCRR. Amendment of Sections 405.3, 415.19, 751.6, 763.13, 3 Amendment of Sections 487.9, 488.9 and 490.9 of Title 	
[] "X" box if the rule was originally proposed as a	consensus rule making.
2. Effective date of rule:	
[X] Date this notice is published in the State Re	egister.
[] This is a "rate making" as defined in SAPA	§102(2)(a)(ii), and, is effective as follows:
[] This is a "rate making" as defined in SAPA [] Date of filing.	§102(2)(a)(ii), and, is effective as follows:
	§102(2)(a)(ii), and, is effective as follows:
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Date of filing.Other date (specify):	§102(2)(a)(ii), and, is effective as follows:
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6. Te	erms and ider	ntification of rule :				
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7. Tf	he text of the	final rule and any req	uired statements a	nd analyses may b	e obtained from	1:
	gency contact	•				
•	Agency name	DOH, Bureau of Pr	ogram Counsel, Reg	. Affairs Unit		
(Office address	Room 2438, ESP To	ower Building, Albar	ıy, NY 12237	ALW I	
	the state of		1 / 1 th			
	Telephone	(518) 473-7488		E-mail: reg	gsqna@health.ny	.gov
8. Ac	dditional matt	er required by statute);	;		
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	C.	[] /	A revised RIS is not attached because this rule is a "rate making" as defined in SAPA §102(2)(a)(ii).
		[]	A revised RIS is not attached because this rule was proposed as a consensus rule as defined in SAPA
10.	Rev (SE	vised LECT	Regulatory Flexibility Analysis (RFA) for small businesses and local governments AND COMPLETE ONE; ALL ATTACHMENTS MUST BE 2,000 WORDS OR LESS)
			attached Revised RFA contains:
		[]	The full text of the Revised RFA.
		[]	A summary of the Revised RFA.
	B	A st	atement is attached explaining why a revised RFA is not required (check one box):
	٥.	[]	Changes made to the last published rule do not necessitate revision to the previously published RFA.
		[]	The changes will not impose any adverse economic impact or reporting, recordkeeping or other compliance requirements on small businesses or local governments. The attached statement sets forth this agency's findings and the reason(s) upon which the findings were made, including what measures were used to determine those findings.
	C.	[]	A revised RFA is not attached because this rule is a "rate making" as defined in SAPA §102(2)(a)(ii).
		[]	A revised RFA is not attached because this rule was proposed as a consensus rule as defined in SAPA §102(11).
11	. R e	evise ELEC	d Rural Area Flexibility Analysis (RAFA) T AND COMPLETE ONE; ALL ATTACHMENTS MUST BE 2,000 WORDS OR LESS)
	A.	The	e attached Revised RAFA contains:
		[]	The full text of the Revised RAFA.
		[]	A summary of the Revised RAFA.
	В.	As	statement is attached explaining why a revised RAFA is not required (check one box):
		[]	Changes made to the last published rule do not necessitate revision to the previously published RAFA.
		[]	The changes will not impose any adverse impact or reporting, recordkeeping or other compliance requirements on public or private entities in rural areas. The attached statement sets forth this agency's findings and the reason(s) upon which the findings were made, including what measures were used to determine those findings.
	С	[]	A revised RAFA is not attached because this rule is a "rate making" as defined in SAPA §102(2)(a)(ii). A revised RAFA is not attached because this rule was proposed as a consensus rule as defined in SAPA §102(11).
1:	(5	SELEC	ed Job Impact Statement (JIS) CT AND COMPLETE ONE; ALL ATTACHMENTS MUST BE 2,000 WORDS OR LESS) e attached Revised JIS contains:
		[]	The full text of the Revised JIS.
		[]	
	В	. A	statement is attached explaining why a revised JIS is not required (check one box):
		[]	Changes made to the last published rule do not necessitate revision to the previously published JIS.
		[]	The changes will not impose a substantial impact on jobs and employment opportunities. The attached statement sets forth this agency's findings that the rule will have a positive impact or no impact on jobs and employment opportunities; except when it is evident from the subject matter of the rule that it could only have a positive impact or no impact on jobs and employment opportunities, the statement shall include a summary of the information and methodology underlying that determination.
	C		revised JIS is not attached because:
			This rule is a "rate making" as defined in SAPA §102(2)(a)(ii).
			This rule was proposed by the State Comptroller or Attorney General.

13. Așse	ssment of Public Comment (includes legislative	comments)			
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[·	Attached is an assessment No particular form is requir published assessment for th received by the agency or a rule (include legislative com significant alternatives sugge incorporated, and a descript An assessment is not attach	of public comment. ed, and it need on is rule. However, th ny comments prese ment). It must conta ested, a statement o ion of any changes led because no con	Ily include con te assessment nted at any pul ain a summary of the reason(s) made as a res	nments not addres must be based on olic hearing held by and an analysis of why any significan oult of such comme	any written comment the agency about the the issues raised an at alternatives were no nts.	ts is id ot
[]	An assessment is not require	red because this ac	ction is for a "ra	ate making" as def	ined in SAPA §102(2	2)
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14. Refere	enced material (check one box) <i>:</i>				
[X	No information is being incor	porated by reference	ce in this rule.			
L	This rule contains referenced	d material in the foll	owing Parts, se	ections, subdivisior	ns or paragraphs:	
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	which is no later t	han the 3 rd year afte	er the year in w	hich this rule is be	ing adopted.	
В. []		RAFA or IIS this	سام بينا المدندة	1 - N		
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C. [X]	As a rule that does not require	e a RFA, RAFA or J	IIS, this rule wi	ll be initially review	ed in the calendar	
	year 2028 , which is no la	ater than the 5th yea	r after the year	in which this rule i	s being adopted.	
D. []	Not Applicable. This is a "rate				* - <u>'</u>	

AGENCY CERTIFICATION (To be completed by the person who PREPARED the notice)

I have reviewed this form and the information submitted with it. The information contained in this notice is correct to the best of my knowledge.

I have reviewed Article 2 of SAPA and Parts 260 through 263 of 19 NYCRR, and I hereby certify that this notice complies with all applicable provisions.

Name	Katherine Ceroalo	Signature
Address	DOH, Bureau of Program Counsel, Reg. Affairs Unit,	Rm 2438, ESP, Tower, Albany, NY 12237
	(518) 473-7488	E-mail regsqna@health.ny.gov
•	09/18/2023	

Please read before submitting this notice:

- 1. Except for this form itself, all text must be typed in the prescribed format as described in the Department of State's *Register* procedures manual, *Rule Making in New York*.
- 2. Rule making notices, with any necessary attachments (in MS Word unless otherwise specified), should be e-filed via the Department of State website.



Governor

Department of Health

JAMES V. McDONALD, M.D., M.P.H. Commissioner JOHANNE E. MORNE, M.S. Acting Executive Deputs Commissione

I HEREBY ADOPT the attached repeal of section 2.61 from Title 10 (Health), amendment of sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 and 1001.11 of Title 10 (Health) and sections 487.9, 488.9 and 490.9 of Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York, pursuant to the authority vested in the Commissioner of Health by sections 225, 2800, 2803, 3612 and 4010 of the Public Health Law and sections 461 and 461-e of the Social Services Law, to be effective upon publication of a Notice of Adoption in the New York State Register.

PRIOR NOTICE OF this action, required under the State Administrative Procedure Act, was published in the New York State Register on June 28, 2023.

IN WITNESS WHEREOF, I have hereunto set my hand and caused the seal of the New York State Department of Health to be affixed this / day of day of 2023.

James V. McDonald M.D., M.P.H. Commissioner of Health



JAMES V. McDONALD, M.D., M.P.H. Commissioner

JOHANNE E. MORNE, M.S. Acting Executive Deputy Commissioner

I HEREBY APPROVE the attached repeal of section 2.61 from Title 10 (Health), amendment of sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 and 1001.11 of Title 10 (Health) and sections 487.9, 488.9 and 490.9 of Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York, was enacted at the meeting of the Public Health and Health Planning Council on September 7, 2023, in New York City, to be effective upon publication of a Notice of Adoption in the New York State Register, pursuant to the authority vested in the Public Health and Health Planning Council by sections 225, 2800, 2803, 3612 and 4010 of the Public Health Law and sections 461 and 461-e of the Social Services Law.

PRIOR NOTICE OF this action, required under the provisions of the State Administrative Procedure Act, was published in the New York State Register on June 28, 2023.

IN WITNESS WHEREOF, I have hereunto affixed my signature this $\sqrt{\theta}$

James V. McDonald M.D., M.P.H.

Commissioner of Health



Governo

Department of Health

JAMES V. McDONALD, M.D., M.P.H. Commissioner

JOHANNE E. MORNE, M.S.: Acting Executive Deputy Commissions.

I HEREBY CERTIFY the attached repeal of section 2.61 from Title 10 (Health), amendment of sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 and 1001.11 of Title 10 (Health) and sections 487.9, 488.9 and 490.9 of Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York, was enacted at the meeting of the Public Health and Health Planning Council on September 7, 2023, in New York City, to be effective upon publication of a Notice of Adoption in the New York State Register, pursuant to the authority vested in the Public Health and Health Planning Council by sections 225, 2800, 2803, 3612 and 4010 of the Public Health Law and sections 461 and 461-e of the Social Services Law.

PRIOR NOTICE OF this action, required under the provisions of the State

Administrative Procedure Act, was published in the New York State Register on June 28, 2023.

IN WITNESS WHEREOF, I have hereunto affixed my signature this 18 day of

September, 2023.

Colleen M. Leonard

Colleen M. Leonard Executive Secretary Public Health and Health Planning Council Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, as well as Social Services Law Sections 461 and 461-e, Title 10 (Health) and Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 2.61 of Title 10 is repealed.

Subparagraph (vi) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 of Title 10 is repealed.

Paragraph (5) of subdivision (a) of Section 415.19 of Part 415 of Title 10 is repealed.

Paragraph (7) of subdivision (d) of Section 751.6 of Title 10 is repealed.

Paragraph (6) of subdivision (c) of Section 763.13 of Title 10 is repealed.

Paragraph (7) of subdivision (d) of Section 766.11 of Title 10 is repealed.

Paragraph (8) of subdivision (d) of Section 794.3 of Title 10 is repealed.

Paragraph (5) of subdivision (q) of Section 1001.11 of Title 10 is repealed.

Paragraph (18) of subdivision (a) of Section 487.9 of Title 18 is repealed.

Paragraph (14) of subdivision (a) of Section 488.9 of Title 18 is repealed.

Paragraph (15) of subdivision (a) of Section 490.9 of Title 18 is repealed.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) Sections 225(5), 2800, 2803(2), 3612 and 4010(4) authorize the Public Health and Health Planning Council (PHHPC) and Commissioner to promulgate regulations: amending the State Sanitary Code; implementing the purposes and provisions of PHL Article 28; with respect to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies; and with respect to hospice organizations.

Social Service Law (SSL) Section 461 authorizes the Department of Health (Department) to promulgate regulations establishing general standards applicable to Adult Care Facilities (ACF).

Legislative Objectives:

The legislative objective of PHL Section 225 empowers PHHPC to address any issue affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises. PHL Article 28 specifically addresses the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. PHL Article 36 addresses the services rendered by certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL

Article 40 declares that hospice is a socially and financially beneficial alternative to conventional curative care for the terminally ill. Lastly, the legislative objective of SSL Section 461 is to promote the health and well-being of residents of ACFs.

Needs and Benefits:

COVID-19 vaccines are safe and effective, and COVID-19 vaccination offers the benefit of helping to reduce the number of COVID-19 infections. The State's regulation requiring covered entities to ensure that personnel are fully vaccinated against COVID-19, has increased the percentage of health care workers who are vaccinated against COVID-19.

However, federal recommendations for COVID-19 vaccination have changed and are expected to evolve as the future course of COVID-19 becomes more apparent. Additionally, there are now effective treatments for COVID-19, case rates appear to have steadily declined, and hospitalizations due to COVID-19 have substantially decreased.

In response to changes in federal recommendations for COVID-19 vaccination and the overall pandemic landscape, the proposed regulation would repeal the requirement that covered entities ensure that personnel are fully vaccinated against COVID-19, as well as repeal the requirement that covered entities document evidence thereof in appropriate records. In lieu of a regulation, covered entities may now individually consider how to implement their own internal policies regarding COVID-19 vaccination, provided they remain in compliance with other applicable state and federal laws and regulations.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

The proposed regulation does not impose any new costs to regulated entities.

Cost to State and Local Government:

The proposed regulation does not impose any new costs to the State or local governments.

Cost to the Department of Health:

There are no additional costs to the State or local government but there may be modest costs savings, since the State and local governments will no longer need to perform surveillance of regulated parties to monitor compliance with the requirement that personnel be fully vaccinated against COVID-19.

Local Government Mandates:

There is no impact on local government mandates associated with this proposed rule change.

Paperwork:

No new paperwork is necessitated by the proposed regulation.

Duplication:

This regulation will not conflict with any state or federal rules.

Alternative Approaches:

One alternative the Department considered was to amend the regulation to require personnel to be "up to date" on COVID-19 vaccinations, rather than "fully vaccinated." However, this option was not considered viable because of the likelihood of continued changes to federal COVID-19 vaccine recommendations and the language surrounding those recommendations. Another alternative that was considered was to allow personnel to wear a well-fitting face covering in lieu of being vaccinated. However, this option was ultimately not chosen because of unknowns surrounding future trends in COVID-19 case rates and because of the likely continuing evolution of federal vaccine recommendations.

Federal Requirements:

On November 5, 2021, the U.S. Department of Health and Human Services' Centers for Medicare & Medicaid Services (CMS) issued an interim final rule (CMS-3415-IFC) requiring Medicare and Medicaid-certified providers and suppliers to ensure that their staff were fully vaccinated for COVID-19 (i.e., obtain the primary vaccination series). On April 10, 2023, the President signed legislation that ended the COVID-19 national emergency and subsequently on May 11, 2023, the COVID-19 public health emergency expired. In light of these developments and comments received on the interim final rule, CMS has stated that it will soon end the requirement that covered providers and suppliers establish policies and procedures for staff vaccination, which would bring the state and federal requirements into alignment.

V: 14

Compliance Schedule:

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register. Effective immediately the Department will cease citing providers for failing to comply with the requirements of 10 NCYRR Section 2.61 while the regulation is in the process of being repealed. The Department may, however, continue to seek sanctions against providers based on previously cited violations that allegedly occurred.

Contact Person:

Ms. Katherine E. Ceroalo

NYS Department of Health

Bureau of Program Counsel, Regulatory Affairs Unit

Corning Tower Building, Room 2438

Empire State Plaza Albany, NY 12237 (518) 473-7488

(518) 473-2019 -FAX

REGSQNA@health.ny.gov

STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS

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.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not required because the amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A Job Impact Statement for these amendments is not necessary because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (Department) received one comment regarding the proposed repeal of the COVID-19 vaccination requirement for personnel in covered entities.

This comment and the Department's response are summarized below.

Comment: The New York City Department of Health and Mental Hygiene urged the Department not to repeal the COVID-19 vaccination requirement for personnel in covered health care facilities and to instead amend the regulation to require personnel in covered entities to be "up to date with their COVID-19 vaccination and wear a mask if they are not, during such times as the State Commissioner of Health determines COVID-19 to be prevalent." The New York City Department of Health and Mental Hygiene stated that such an amendment would reduce the risk of COVID-19 transmission to patients, many of whom may be at increased risk for severe COVID-19 outcomes; help protect health care infrastructure; and align COVID-19 health care setting vaccination requirements with those for influenza.

Response: The Department carefully considered amending the regulation to require personnel to be "up to date" on COVID-19 vaccinations, rather than "fully vaccinated." However, this change was not made because of the likelihood of continued changes to federal COVID-19 vaccine recommendations and the uncertainty of such recommendations in the future. The Department also considered allowing personnel to wear a well-fitting face covering in lieu of being vaccinated against COVID-19. However, this option was ultimately not chosen because of unknowns surrounding future trends in COVID-19 case rates and because of the likely continuing evolution of federal vaccine recommendations. Unlike influenza, COVID-19 has not

completely established a seasonality and requiring health care facilities to track both influenza and COVID-19 vaccination status and/or mask wearing for all personnel would create significant logistical challenges for healthcare facilities. By repealing the regulation, health care facilities will be able to determine on their own whether to implement a COVID-19 vaccination requirement or a face-covering requirement. The Department is continually monitoring the spread and mutations of COVID-19 and will keep these comments in mind should future rulemaking on the matter be necessary. No changes to the proposed regulation have been made as a result of these comments.

Attachment 2: Confirmation from Department of State

doh.sm.REGSQNA

From:

West Group Data Capture System < west.clandestine@thomson.com>

Sent:

Monday, September 18, 2023 4:26 PM

To:

doh.sm.REGSQNA

Subject:

[Receipt # 199370449, Submitting Agency: hlt]: Submission was successful

ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.

Your submitted files were:

HLT-ADOPT-2.61--405.3--415.19--751.6--763.13--766.11--794.3--1001.11-&-487.9--488.9--490.9.pdf - Verified

Note: This email is sent from an unattended mailbox. Please do not reply to this email as it is likely no one will read your response. Thank You.

doh.sm.REGSQNA

FROM-PHOENIX-DO-NOT-REPLY@thomson.com

Sent: Monday, September 18, 2023 4:27 PM

To: doh.sm.REGSQNA; west.PhoenixDevSupport@thomson.com

Cc: doh.sm.REGSQNA; West.domaintestingcoordinator@thomson.com; dos.sm.DAR.Rules

Subject: NOTICE OF UPLOADED SUCCESSFULLY

ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.

NOTICE OF ACCEPTANCE

The following notices have been accepted by the electronic filing system for the State Register:

199370449_HLT-ADOPT-2.61--405.3--415.19--751.6--763.13--766.11--794.3--1001.11-&-487.9--488.9--490.9.pdf

You will receive a filing acknowledgement from the Division of Administrative Rules once the contents of your filings have been verified.

Ceroalo, Katherine E (HEALTH)

From:

dos.sm.DAR.Rules

Sent:

Tuesday, September 19, 2023 9:15 AM

To:

Ceroalo, Katherine E (HEALTH)

Subject:

Acknowledgment

Attachments:

HLT26001.txt

9/19/2023 Katherine Ceroalo Office of Regulatory Affairs, Rm. 2438 Corning Tower Albany, NY 12237

RE: Acknowledgement

The Department of State's Division of Administrative Rules has received the following

notice that will be published in issue 40 of the State Register 10/04/2023 Notice of Adoption

SECTIONS 2.61, 405.3, 415.19, 751.6, 763.13, 766.11, 794.3, 1001.11 OF 10 NYCRR; SECTIONS 487.9, 488.9, 490.9 OF TITLE 18 NYCRR Rule # HLT262300001