Supplementary Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.

eMethods

I. Excluding hospital types that were not shared in both New York State and control states

To create a more homogenous sample of hospitals across states, we categorized hospitals based on the following characteristics: bed size (<100, 100 to 250, or >250); academic status by resident full-time equivalent to bed size ratio (non-teaching = ratio of 0; small teaching = ratio between 0 and 0.2; large teaching = ratio of 0.2 or higher); and regional population (small = non-metropolitan statistical area or metropolitan statistical area population <100,000; medium = metropolitan statistical area population 100,000 to 1 million; large = metropolitan statistical area population >1 million). With three characteristics and three categories for each characteristic, there were a total of 3x3x3=27 possible characteristic combination groups. We excluded hospitals in groups that appeared only in the control states or only in New York State, in either the pre-intervention period or in the post-intervention period. The goal of this process was to exclude "outlier" hospital types and ensure that we could adequately control for hospital characteristics in the multivariable models.

II. Detailed model specifications

To understand the association between the regulation and patient outcomes, we used a comparative interrupted time series approach. This approach tests if outcomes in New York deviated from a pre-intervention trend by a greater amount than in control states. We considered the pre-intervention period to be from January 1, 2011 through March 31, 2013, i.e. the period of time before the official filing of the regulations. The base model includes a continuous time variable (allowing for secular changes in outcome over time, independent of any intervention), an interaction term between the continuous time variable and treatment (allowing for the pre-intervention trends to differ between New York and control states), indicators for each post-intervention quarter (representing quarter-specific estimates in the post-intervention period), and a term for the interaction between the indicators and treatment (allowing the quarter-specific estimates to vary across New York and control states). The models also controlled for patient characteristics and hospital characteristics as described in the print methods, as well as seasonality based on calendar quarter (implemented as a "season" term alone and interacted with the treatment indicator).

This model is specified as:

$$Y_{ijt} = \eta_0 + \eta_1 NY_j + \tau_0 Time_t + \tau_1 (NY_j Time_t) + \sum_{p=1}^{P} \left(\alpha_p Post_{pt} + \beta_p (NY_{ij} Post_{pt}) \right) + \sum_{q=2}^{4} \left(\phi_{0q} Season_q + \phi_{1q} (NY_j Season_q) \right) + \sum_{v=1}^{V} \lambda_v X_{vij} + \epsilon_{ijt}$$

where Y_{ijt} is the outcome of interest (e.g., mortality), NY_j is an indicator equal to 1 for hospitals in New York, $Time_t$ is a continuous time variable (in quarters) centered at the last pre-intervention quarter, $Post_{pt}$ is an indicator equal to 1 if time is the p^{th} post-intervention quarter, $Season_q$ is an indicator for season based on calendar quarter, X_{vij} are the patient- and hospital-level covariates to be adjusted for, and ϵ_{ijt} is a patient level error term.

In this model the point estimate on each interaction term (β_p) is interpreted as the estimated association between the regulations and patient outcomes in the given post-intervention quarter, representing the difference in deviation from the pre-intervention trends between New York and control states in that quarter. As the primary test of the association between the regulations and patient outcomes, we performed a joint test of the null hypothesis that all of the quarter specific estimates were equal to zero.

To allow a marginal interpretation of our model parameters, we used a linear probability model for all analyses. Our models addressed non-standard variance-covariance structures, which may have varied for two reasons. First, for binary outcomes, we had heteroskedastic error terms because the variance is a quadratic function of the true event percentages and attains its maximum at 50%. Second, outcomes of patients within a hospital were expected to be correlated. We accounted for these non-standard variance-covariance structures by using robust standard errors clustered at the hospital level. All coefficients were modelled as fixed effects.

This comparative interrupted time series approach offers several benefits over more traditional approaches such as a difference-in-differences model. First, this approach does not require us to assume that the association between the regulations and patient outcomes is constant over time or to exclude

data from a phase-in period of an arbitrary length. Rather, it allows the association between an intervention and outcomes to differ over time as the different elements are rolled out without excluding any data as a phase-in period. Put another way, this model would allow the association between the intervention and outcomes to be small initially and increase over time, or be large initially and wane with time. This decision is important because the introduction and implementation of Rory's Regulations was staged, spanning several years (**Table S3**).

Second, this approach does not require us to assume that the pre-intervention trends are parallel between New York and control states. Although we carefully chose our control states based on their similarities to New York in terms of their demographics and policy landscapes, it was still possible that pre-intervention trends in outcomes might differ over time, necessitating a more flexible approach. That said, we pre-specified the option of simplifying our model to a difference-in-differences model for cases in which pre-intervention trends were similar between New York State and control states.

To test whether these trends were similar, we fit a model with a treatment indicator, a continuous time variable (implemented as quarters), and the interaction of these two variables. In this model we also controlled for seasonality, patient characteristics, and hospital characteristics as described in the print methods. Here we did not include terms for post-intervention quarters since this analysis included the pre-intervention period only. The model specification was:

$$Y_{ijt} = \eta_0 + \eta_1 NY_j + \sigma_0 Time_t + \sigma_1\left(NY_j Time_t\right) + \sum_{q=2}^{4}\left(\phi_{0q} Season_q + \phi_{1q}\left(NY_j Season_q\right)\right) + \sum_{v=1}^{V}\lambda_v X_{vij} + \epsilon_{ijt}$$

The coefficient of interest is from the interaction term (σ_1), which measures the difference in time trend between New York and control states in the pre-intervention period. If this coefficient is not statistically significant, then we assumed that the pre-intervention trends were parallel and we simplified to a difference-in-differences model by removing the interaction term between the continuous time variable and intervention group. This model specification was as follows, for patient *i*, in hospital *j*, at time *t*:

$$Y_{ijt} = \eta_0 + \eta_1 NY_j + \tau_0 Time_t + \sum_{p=1}^{P}\left(\alpha_p Post_{pt} + \beta_p\left(NY_j Post_{pt}\right)\right) + \sum_{q=2}^{4}\left(\phi_{0q} Season_q + \phi_{1q}\left(NY_j Season_q\right)\right) + \sum_{v=1}^{V}\lambda_v X_{vij} + \epsilon_{ijt}$$

where Y_{ijt} is the outcome of interest (e.g., mortality), NY_j is an indicator equal to 1 for hospitals in New York, $Time_t$ is a continuous time variable (in quarters) centered at the last pre-intervention quarter, $Post_{pt}$ is an indicator equal to 1 if time is the p^{th} post-intervention quarter, $Season_q$ is an indicator for season based on calendar quarter, X_{vij} are the patient- and hospital- level covariates to be adjusted for, and ϵ_{ijt} is a patient level error term.

Along with each model's results, we also show the p-value for the test of parallel trends and state whether, based on this test, we used a comparative interrupted time series model or a difference-in-differences model.

III. Deviations from the pre-specified analysis plan and their rationale

In an effort to support the rigor and transparency of our results, we pre-published our complete statistical analysis plan on Open Science Framework prior to receipt of the final data set (https://osf.io/jcwdv/). However, in our pre-published plan we acknowledged the possibility that we might need to alter our plans due to unforeseen circumstances. Here, we provide the details of such instances, along with the rationale for the changes.

1. Lack of inclusion of Pennsylvania as a control state. In the pre-published statistical analysis plan, we indicated that we would add Pennsylvania as a control state if the data were available. Pennsylvania makes its hospital discharge data available for research through an independent body (the Pennsylvania Health Care Cost Containment Council—PHC4) rather than the HCUP central distributer. At the time of the analyses, we did not yet have access to 2015 data, necessitating this change.

2. Retention of a continuous quarter variable in our final models: In the pre-published statistical analysis plan, we indicated that we would first fit our models using a continuous quarter variable, but if this variable was not significant we would drop it, thus creating a more parsimonious model. However, when we attempted to drop this variable, the post-estimation commands necessary to generate predictive margins were not estimable. Thus, we elected to retain this variable in all models. Since inclusion of a non-statistically significant variable would be unlikely to change any of our results, and, due to loss of precision, inclusion of the variable is a more conservative modelling approach compared to the alternative, this change is unlikely to result in bias.

3. Subgroup analyses performed only for main outcome of mortality: In the pre-published statistical analysis plan, we indicated that we would perform subgroup analyses for both our primary outcome variable and our four secondary outcome variables. However, upon seeing our primary results we did not think that subgroup analyses on the secondary outcomes would be sufficiently informative to justify the risk of false discovery, even after adjusting for multiple comparisons. Therefore we opted to not perform these analyses.

4. Post hoc analysis to understand variation in ICU admission rates across states: We were not expecting to observe substantial differences in baseline ICU admission rates between New York State and control states for patients with sepsis (see **Table 2** in the main manuscript). These differences were apparent only after receipt of the data. To better understand these differences, we performed a post hoc analysis of ICU admission rates stratified by ICU bed availability. The goal of this post hoc analysis was to provide reassurance that we were adequately controlling for differences in case-mix in our adjusted models, which included both patient and hospital characteristics. The results of this analysis are shown in **eTable 3**. This analysis was for informational purposes only and did not change our pre-specified approach.

5. Post hoc analysis to understand variation in central line insertion rates across states: We were not expecting to observe large differences in baseline central line insertion rates between New York State and control states for patients with sepsis (see **Table 2** in the main manuscript). These differences were apparent only after receipt of the data. To better understand these differences, we performed a post hoc analysis of central line insertion rates stratified by ICU admission category. The goal of this post hoc analysis was to provide reassurance that we were adequately controlling for differences in case-mix in our adjusted models, which included both patient and hospital characteristics. The results of this analysis are shown in **eTable 4**. This analysis was for informational purposes only and did not change our pre-specified approach.

6. Post hoc analysis to understand the robustness of our results to the choice of control states: We expected sepsis mortality to be decreasing over time both in New York and control states, and we accounted for the possibility that these declines might not be equal by pre-specifying a comparative interrupted time series model, which allows for different pre-regulation temporal trends. However, given the observed differences, we sought to examine the degree to which our results were sensitive to our choice of control states. To do this we sequentially excluded states with the largest differences in pre-regulation mortality trends compared to New York. The results of this analysis are shown in **eTable 15**. This analysis was performed as a sensitivity check and did not change our primary, pre-specified analysis.

eTable 1. Full list of variables and their definitions.

Note: Variables obtained directly from HCUP data sets are denoted using the HCUP variable name in all caps in the definition column. Diagnosis and procedure codes are based on the *International Classification of Diseases—9th Revision, Clinical Modification* (ICD-9-CM). The suffix * indicates that any code beginning with the given value was included, as applicable. For example, 421* includes 421, 4210, 4211, and 4219.

Variable	**Definition**
Sepsis – main definition (modified Dombrovskiy)	Organ dysfunction by any diagnosis (DXn) of 2866, 2869, 2874, 2875, 2930, 3481, 3483, 4275, 4580, 4588, 4589, 51881, 51882, 570, 5722, 5734, 584*, 78081, 7855*, 78609, 7963, or 7991 Plus infection by any diagnosis (DXn) of 0031*, 0202*, 0223*, 0362*, 0363*, 0380*, 0381*, 0382*, 0383*, 0384*, 0388*, 0389*, 0545*, 09889, 1125*, 78552, 99591, 99592. Or any diagnosis (with or without an organ dysfunction) of 78552 or 99592
Hospital length of stay	LOS
In hospital mortality by day 30	DISPUNIFORM = 20 (i.e. discharge disposition of “died”) and LOS <= 30
ICU admission	UB-04 Revenue Codes for Intensive care (0200-0209) and/or Coronary care (0210-0219) For states other than Florida: U_ICU=1 and/or U_CCU=1; For Florida: any non-zero non-missing charges recorded for CHG5 and/or CHG6
Central line insertion	Any procedure (PRn) of 3893, 3895, or 3897
C. difficile infection	Any diagnosis (DXn) of 00845
Age	AGE
Sex	FEMALE
Race/Ethnicity	RACE as categorized for white, black, and Hispanic; other = Asian or Pacific Islander, Native American, or Other. Race and ethnicity were taken from the fixed categories in the HCUP database as ascertained by the reporting hospitals.
Outside hospital transfer	TRAN_IN=1
Emergency department use	For states other than Florida, U_ED=1; For Florida, any non-zero non-missing charges recorded for CHG18
Comorbidities	Per HCUP Clinical Classification software, available online at https://www.hcup-us.ahrq.gov/toolssoftware/comorbidity/comorbidity.jsp

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eTable 1 (continued).

Variable	Definition
Organ failures on admission	Any diagnosis (DXn) as listed below with correlated present on admission indicator (DXPOAn) equal to "Y" Respiratory Failure: 51881, 51882, 51885, 78609, 7991 Cardiovascular Failure: 4580, 4588, 4589, 7855, 78551, 78559, 7963 Renal Failure: 580, 584, 5845, 5846, 5847, 5848, 5849 Liver Failure (Hepatic): 570, 5722, 5733 Coagulopathy (Hematologic): 2862, 2866, 2869, 2873, 2874, 2875 Acidosis (Metabolic): 2762 Neurologic: 293, 3481, 3483, 78001, 78009
Infection categories, Angus infection codes	Any diagnosis (DXn) as listed below, with the hierarchy in the order listed Septicemia: 038*, 99591 Heart: 420*, 421* Peritoneum: 567*, 56983, 00845 Lung: 010*, 011*, 012*, 0310*, 481*, 482*, 485*, 486* Fungal: 1120*, 1124*, 1125*, 114*, 115*, 116*, 117*, 118* Blood: 018*, 7907*, 0312* CNS: 013*, 036*, 094*, 320*, 322*, 3240*, 3241*, 3249*, 325* Other: 001*, 002*, 004*, 005*, 008* except 00845, 009*, 020*, 021*, 022*, 023*, 024*, 025*, 026*, 027*, 030*, 0318*, 0319*, 032*, 033*, 034*, 037*, 039*, 040*, 041*, 0545*, 090*, 091*, 092*, 093*, 095*, 096*, 097*, 100*, 101*, 102*, 103*, 104*, 1121*, 1122*, 1128*, 1129*, 49121, 494*, 510*, 513*, 730*, 9966*, 9985*, 9993* GU: 016*, 098*, 590*, 597*, 5990*, 601*, 614*, 615*, 616* Skin: 015*, 017*, 0311*, 035*, 110*, 111*, 1123*, 451*, 681*, 682*, 683*, 686*, 7110*, 730* GI: 003*, 014*, 540*, 541*, 542*, 56201, 56203, 56211, 56213, 566*, 5695*, 5720*, 5721*, 5750* Throat: 461*, 462*, 463*, 464*, 465*
Sepsis – sensitivity analysis definition, modified Angus	Any infection as listed above plus organ dysfunction by any diagnosis (DXn) of 2866*, 2869*, 2874*, 2875*, 293*, 3481*, 3483*, 458*, 570*, 5734*, 584*, 7855* but not 78552, or by any procedure (PRn) of 967* Or any diagnosis (with or without an organ dysfunction) of 78552 or 99592
Hierarchical infection categories, overall	As above with the following additions Septicemia: 78552, 99592
Sepsis – sensitivity analysis definition, explicit codes	Any diagnosis (DXn) of 78552 or 99592
Continuous time variable	Based on DQTR and YEAR
Season variable	Based on DQTR

eTable 2. Complete policy timeline

Month and year	Event
April, 2012	Rory Staunton died from sepsis leading to media coverage in the summer of 2012
January, 2013	New York Governor Andrew Cuomo announced that Rory's Regulations would be developed
April, 2013	Regulations filed
May, 2013	Regulations adopted
September 1, 2013	Hospitals required to submit sepsis protocols for review by the NY state Department of Health
December 31, 2013	Hospitals required to begin protocol implementation
April to June, 2014	Hospitals required to begin reporting patient-level data on protocol adherence and outcomes to the state
July to September, 2014	Hospitals received their first performance feedback from the NY State Department of Health

eTable 3. Post hoc analysis of ICU admission rates. The table shows ICU admission rates stratified by the ICU size of the admitting hospital.

Note: This post hoc analysis was performed to better understand baseline differences in ICU admission rates between New York State and control states. The table shows that although control states had relatively higher ICU admission rates for patients with sepsis, this difference was in part driven by differences in ICU bed availability across states.

	New York state		**Control states**	
	Pre-regulation (N = 139,019)	Post-regulation (N = 186,767)	Pre-regulation (N = 289,225)	Post-regulation (N = 397,399)
ICU admission rates				
Overall	82,345 (59.2%)	104,846 (56.1%)	221,082 (76.4%)	297,776 (74.9%)
By ICU size				
≤ 10 beds	6,609 (52.3%)	7,715 (50.4%)	10,991 (65.4%)	13,663 (62.5%)
11 to 25 beds	13,937 (63.4%)	16,493 (61.6%)	50,748 (70.5%)	62,939 (68.8%)
> 25 beds	61,799 (59.2%)	80,638 (55.7%)	159,343 (79.5%)	221,174 (77.9%)

eTable 4. Post hoc analysis of central line insertion rates. The table shows central line insertion rates stratified by ICU admission.

Note: This post hoc analysis was performed to better understand baseline differences in central line insertion rates between New York State and control states. The table shows that although control states had relatively higher central line insertion rates for patients with sepsis, this difference was in part driven by differences in ICU admission status.

	New York state		**Control states**	
	Pre-regulation (N = 139,019)	Post-regulation (N = 186,767)	Pre-regulation (N = 289,225)	Post-regulation (N = 397,399)
Central line use				
Overall	51,814 (37.3%)	66,420 (35.6%)	138,906 (48.0%)	171,702 (43.2%)
By ICU admissions status				
Admitted to the ICU	40,342 (49.0%)	50,825 (48.5%)	121,648 (55.0%)	150,253 (50.5%)
Not admitted to the ICU	11,472 (20.2%)	15,595 (19.0%)	17,258 (25.3%)	21,449 (21.5%)

eTable 5. Adjusted 30-day in hospital mortality rates and the counterfactual rates assuming pre-regulation temporal trends continued, both for New York State and Control States, along with the adjusted estimates for the association between the regulations and mortality in each quarter.

Note: These data are a tabular representation of the data shown in Figure 1.

	New York State (% mortality)		Control States (% mortality)		
Quarter	**Observed**	**Counterfactual**	**Observed**	**Counterfactual**	**Estimate (95%CI)**
Q1 2013	24.5		21.0		
Q2 2013	22.9	24.3	21.2	20.7	-2.0 (-3.2 to -0.7)
Q3 2013	23.2	24.2	20.8	20.4	-1.4 (-2.8 to 0.0)
Q4 2013	22.3	24.0	19.9	20.0	-1.6 (-2.9 to -0.3)
Q1 2014	22.0	23.9	19.8	19.7	-2.0 (-3.4 to -0.6)
Q2 2014	22.4	23.7	19.8	19.4	-1.8 (-3.6 to 0.0)
Q3 2014	22.3	23.6	19.3	19.0	-1.6 (-3.3 to 0.1)
Q4 2013	21.3	23.4	18.9	18.7	-2.3 (-3.9 to -0.6)
Q1 2015	20.9	23.3	18.4	18.4	-2.4 (-4.5 to -0.3)
Q2 2015	20.2	23.1	18.8	18.0	-3.7 (-6.0 to -1.5)
Q3 2015	20.5	23.0	18.4	17.7	-3.2 (-5.4 to -1.0)
Test of parallel trends[a]					P = 0.01
Model					CITS
Joint test of significance					P = 0.02

Q = Quarter; CITS = comparative interrupted time series

[a] Parallel trends in the pre-regulation period were tested using a model containing a treatment indicator, a continuous time variable, the interaction of these two variables, and all patient- and hospital-level covariates, restricting to the pre-regulation period. The reported p-values are from the test of significance of the interaction term from this model. In cases where the interaction term was statistically significantly different from zero, a comparative interrupted time series model was used. Otherwise, parallel temporal trends in the pre-regulation period were assumed and a modified difference-in-differences model was used. These model decisions are outlined in the pre-specified statistical analysis plan.

eTable 6. Adjusted ICU admission rates and the counterfactual rates assuming pre-regulation temporal trends continued, both for New York State and control states, along with the adjusted estimates for the association between the regulations and ICU admission rate in each quarter.

Note: These data are a tabular representation of the data shown in Figure 2.

	New York State (% admitted to ICU)		Control States (% admitted to ICU)		
Quarter	**Observed**	**Counterfactual**	**Observed**	**Counterfactual**	**Estimate (95%CI)**
Q1 2013	59.5		76.0		
Q2 2013	60.0	59.1	75.6	76.0	1.2 (-0.5 to 3.0)
Q3 2013	59.6	58.8	75.8	76.0	0.9 (-1.2 to 3.1)
Q4 2013	59.1	58.4	76.1	75.9	0.5 (-1.9 to 3.0)
Q1 2014	58.3	58.1	75.6	75.9	0.6 (-2.2 to 3.5)
Q2 2014	56.0	57.7	75.2	75.9	-0.9 (-4.3 to 2.4)
Q3 2014	57.6	57.4	74.6	75.9	1.5 (-2.2 to 5.2)
Q4 2013	56.2	57.0	73.4	75.9	1.6 (-2.0 to 5.3)
Q1 2015	55.2	56.7	72.8	75.8	1.6 (-2.3 to 5.5)
Q2 2015	55.2	56.3	72.4	75.8	2.3 (-2.0 to 6.6)
Q3 2015	54.8	55.9	71.9	75.8	2.8 (-1.7 to 7.2)
Test of parallel trends[a]					P = 0.04
Model					CITS
Joint test of significance					P = 0.09

ICU = intensive care unit; Q = Quarter; CITS = comparative interrupted time series

[a] Parallel trends in the pre-regulation period were tested using a model containing a treatment indicator, a continuous time variable, the interaction of these two variables, and all patient- and hospital-level covariates, restricting to the pre-regulation period. The reported p-values are from the test of significance of the interaction term from this model. In cases where the interaction term was statistically significantly different from zero, a comparative interrupted time series model was used. Otherwise, parallel temporal trends in the pre-regulation period were assumed and a modified difference-in-differences model was used. These model decisions are outlined in the pre-specified statistical analysis plan.

eTable 7. Adjusted hospital lengths stay and the counterfactual lengths of stay assuming pre-regulation temporal trends continued, both for New York State and control states, along with the adjusted estimates for the association between the regulations and hospital length of stay in each quarter.

Note: These data are a tabular representation of the data shown in Figure 2.

	New York State (Length of stay in days)		Control States (Length of stay in days)		
Quarter	**Observed**	**Counterfactual**	**Observed**	**Counterfactual**	**Estimate (95%CI)**
Q1 2013	14.4		12.1		
Q2 2013	14.8	14.2	11.7	14.8	0.9 (0.3 to 1.4)
Q3 2013	14.4	14.1	11.9	14.4	0.4 (-0.2 to 1.0)
Q4 2013	13.8	13.9	11.7	13.8	0.1 (-0.5 to 0.6)
Q1 2014	13.5	13.7	11.9	13.5	-0.2 (-0.9 to 0.4)
Q2 2014	14.2	13.5	11.7	14.2	0.7 (-0.1 to 1.6)
Q3 2014	14.0	13.4	11.8	14.0	0.5 (-0.2 to 1.3)
Q4 2013	13.4	13.2	11.7	13.4	0.2 (-0.5 to 0.9)
Q1 2015	13.5	13.0	11.8	13.5	0.3 (-0.6 to 1.2)
Q2 2015	13.4	12.8	11.5	13.4	0.6 (-0.4 to 1.6)
Q3 2015	13.3	12.6	11.6	13.3	0.5 (-0.5 to 1.5)
Test of parallel trends[a]					P = 0.004
Model					CITS
Joint test of significance					P = 0.04

Q = Quarter; CITS = comparative interrupted time series

[a] Parallel trends in the pre-regulation period were tested using a model containing a treatment indicator, a continuous time variable, the interaction of these two variables, and all patient- and hospital-level covariates, restricting to the pre-regulation period. The reported p-values are from the test of significance of the interaction term from this model. In cases where the interaction term was statistically significantly different from zero, a comparative interrupted time series model was used. Otherwise, parallel temporal trends in the pre-regulation period were assumed and a modified difference-in-differences model was used. These model decisions are outlined in the pre-specified statistical analysis plan.

eTable 8. Adjusted central venous catheter rates and the counterfactual rates assuming pre-regulation temporal trends continued, both for New York State and control states, along with the adjusted estimates for the association between the regulations and central venous catheter use in each quarter.

Note: These data are a tabular representation of the data shown in Figure 2.

	New York State (% with CVC)		Control States (% with CVC)		
Quarter	**Observed**	**Counterfactual**	**Observed**	**Counterfactual**	**Estimate (95%CI)**
Q1 2013	37.6		46.5		
Q2 2013	37.8	37.3	46.8	46.2	-0.2 (-1.9 to 1.6)
Q3 2013	37.6	37.0	45.3	45.9	1.2 (-0.5 to 2.9)
Q4 2013	37.3	36.7	44.9	45.6	1.2 (-0.4 to 2.9)
Q1 2014	37.5	36.4	44.6	45.3	1.8 (0.0 to 3.6)
Q2 2014	36.2	36.1	43.9	45.0	1.2 (-0.9 to 3.3)
Q3 2014	36.5	35.8	43.0	44.7	2.3 (0.5 to 4.2)
Q4 2013	35.3	35.5	41.4	44.4	2.8 (0.8 to 4.9)
Q1 2015	34.9	35.2	40.8	44.1	3.0 (1.0 to 5.0)
Q2 2015	33.9	34.9	40.4	43.8	2.4 (0.0 to 4.9)
Q3 2015	34.5	34.6	38.6	43.5	4.8 (2.3 to 7.4)
Test of parallel trends[a]					P = 0.80
Model					DID
Joint test of significance					P = 0.02

CVC = central venous catheter; Q = Quarter; DID = difference-in-differences

[a] Parallel trends in the pre-regulation period were tested using a model containing a treatment indicator, a continuous time variable, the interaction of these two variables, and all patient- and hospital-level covariates, restricting to the pre-regulation period. The reported p-values are from the test of significance of the interaction term from this model. In cases where the interaction term was statistically significantly different from zero, a comparative interrupted time series model was used. Otherwise, parallel temporal trends in the pre-regulation period were assumed and a modified difference-in-differences model was used. These model decisions are outlined in the pre-specified statistical analysis plan.

eTable 9. Adjusted *C. difficile* rates and the counterfactual rates assuming pre-regulation temporal trends continued, both for New York State and control states, along with the adjusted estimates for the association between the regulations and *C. difficile* in each quarter.

Note: These data are a tabular representation of the data shown in Figure 2.

	New York State (% with *C. diff*)		Control States (% with *C. diff*)		
Quarter	**Observed**	**Counterfactual**	**Observed**	**Counterfactual**	**Estimate (95%CI)**
Q1 2013	9.1		7.9		
Q2 2013	8.8	9.0	7.9	7.8	-0.3 (-1.1 to 0.5)
Q3 2013	7.8	8.9	7.9	7.7	-1.3 (-2.1 to -0.6)
Q4 2013	8.2	8.8	7.4	7.6	-0.4 (-1.1 to 0.3)
Q1 2014	7.6	8.7	7.0	7.5	-0.7 (-1.4 to 0.1)
Q2 2014	7.4	8.7	6.8	7.4	-0.6 (-1.4 to 0.2)
Q3 2014	7.3	8.6	7.4	7.4	-1.3 (-2.2 to -0.4)
Q4 2013	7.3	8.5	6.8	7.3	-0.7 (-1.5 to 0.1)
Q1 2015	6.3	8.4	7.0	7.2	-1.9 (-2.7 to -1.1)
Q2 2015	6.7	8.3	6.7	7.1	-1.1 (-2.0 to -0.3)
Q3 2015	6.3	8.2	6.9	7.0	-1.8 (-2.6 to -1.0)
Test of parallel trends					P = 0.38
Model					DID
Joint test of significance					P ≤ 0.001

Q = Quarter; DID = difference-in-differences

[a] Parallel trends in the pre-regulation period were tested using a model containing a treatment indicator, a continuous time variable, the interaction of these two variables, and all patient- and hospital-level covariates, restricting to the pre-regulation period. The reported p-values are from the test of significance of the interaction term from this model. In cases where the interaction term was statistically significantly different from zero, a comparative interrupted time series model was used. Otherwise, parallel temporal trends in the pre-regulation period were assumed and a modified difference-in-differences model was used. These model decisions are outlined in the pre-specified statistical analysis plan.

eTable 10. Supplementary analysis examining the association between the regulations and sepsis coding

Note: The goal of this analysis was to understand the potential association between f the regulations and sepsis coding. If the regulations were associated with sepsis coding it could have introduced endogeneity, since the regulations could then have been associated with the size and characteristics of the population under study. For these analyses the population was all adult hospital admissions, the dependent variable was whether the admission was coded as sepsis using the primary definition, and the independent variables were patient and hospital characteristics. The p-value for the joint test of significance was >0.05, indicating no significant relationship between the regulations and sepsis coding. The table shows the adjusted quarter and group-specific percentages, along with the adjusted estimates and their 95% confidence intervals.

	New York State (% with sepsis)		**Control States (% with sepsis)**		
Quarter	**Observed**	**Counterfactual**	**Observed**	**Counterfactual**	**Estimate (95%CI)**
Q1 2013	3.6		3.1		
Q2 2013	3.7	3.6	3.2	3.2	0.0 (-0.2 to 0.1)
Q3 2013	3.7	3.7	3.3	3.2	0.0 (-0.2 to 0.2)
Q4 2013	3.9	3.7	3.4	3.2	0.0 (-0.1 to 0.2)
Q1 2014	4.1	3.7	3.5	3.2	0.1 (-0.1 to 0.3)
Q2 2014	4.1	3.8	3.5	3.3	0.1 (-0.2 to 0.3)
Q3 2014	4.1	3.8	3.6	3.3	0.0 (-0.2 to 0.2)
Q4 2013	4.2	3.8	3.7	3.3	0.0 (-0.2 to 0.2)
Q1 2015	4.4	3.8	3.8	3.4	0.1 (-0.1 to 0.3)
Q2 2015	4.3	3.9	3.8	3.4	0.0 (-0.3 to 0.2)
Q3 2015	4.3	3.9	3.9	3.4	0.0 (-0.3 to 0.2)
Test of parallel trends[a]					P = 0.46
Model					DID
Joint test of significance					P = 0.59

Q = Quarter; DID = difference-in-differences

[a] Parallel trends in the pre-regulation period were tested using a model containing a treatment indicator, a continuous time variable, the interaction of these two variables, and all patient- and hospital-level covariates, restricting to the pre-regulation period. The reported p-values are from the test of significance of the interaction term from this model. In cases where the interaction term was statistically significantly different from zero, a comparative interrupted time series model was used. Otherwise, parallel temporal trends in the pre-regulation period were assumed and a modified difference-in-differences model was used. These model decisions are outlined in the pre-specified statistical analysis plan.

eTable 11. Sensitivity analysis defining sepsis using explicit sepsis codes

Note: The goal of this analysis was to understand the robustness of the main results to a different identification strategy for sepsis, in this case using the "explicit" ICD-9-CM codes for severe sepsis and septic shock. This definition is narrower than the primary definition and captures a patient group with relatively higher illness severity (and thus higher baseline mortality). It also has a more negative predictive value than the primary definition. The dependent variable is in-hospital mortality by day 30, and the independent variables are as described in the print methods. The p-value for the joint test of significance was <0.05, indicating a significant association between the regulations and sepsis mortality using this alternative definition. The table shows the adjusted quarter and group-specific percentages, along with the adjusted estimates and their 95% confidence intervals.

	New York State (% mortality)		**Control States (% mortality)**		
Quarter	**Observed**	**Counterfactual**	**Observed**	**Counterfactual**	**Estimate (95%CI)**
Q1 2013	30.1		26.2		
Q2 2013	28.1	30.0	26.6	25.7	-2.8 (-4.4 to -1.1)
Q3 2013	28.5	29.8	26.0	25.3	-2.0 (-3.8 to -0.2)
Q4 2013	27.6	29.7	25.3	24.9	-2.4 (-4.1 to -0.7)
Q1 2014	27.4	29.6	24.7	24.5	-2.4 (-4.0 to -0.8)
Q2 2014	28.4	29.4	25.0	24.1	-1.9 (-4.1 to 0.4)
Q3 2014	27.8	29.3	24.1	23.7	-1.8 (-3.9 to 0.3)
Q4 2013	27.2	29.1	23.7	23.3	-2.3 (-4.4 to -0.3)
Q1 2015	26.4	29.0	23.3	22.9	-3.1 (-5.5 to -0.6)
Q2 2015	25.9	28.8	23.9	22.5	-4.4 (-7.2 to -1.7)
Q3 2015	26.0	28.7	23.4	22.1	-4.0 (-6.7 to -1.3)
Test of parallel trends[a]					P = 0.003
Model					CITS
Joint test of significance					P = 0.005

Q = Quarter; CITS = comparative interrupted time series

[a] Parallel trends in the pre-regulation period were tested using a model containing a treatment indicator, a continuous time variable, the interaction of these two variables, and all patient- and hospital-level covariates, restricting to the pre-regulation period. The reported p-values are from the test of significance of the interaction term from this model. In cases where the interaction term was statistically significantly different from zero, a comparative interrupted time series model was used. Otherwise, parallel temporal trends in the pre-regulation period were assumed and a modified difference-in-differences model was used. These model decisions are outlined in the pre-specified statistical analysis plan.

eTable 12. Sensitivity analysis defining sepsis using the modified Angus codes

Note: The goal of this analysis was to understand the robustness of the results to a different identification strategy for sepsis, in this case using the modified Angus codes for infection and organ failure. This definition is broader than the primary definition and captures a patient group with relatively lower illness severity (and thus lower baseline mortality). It also has a lower positive predictive value than the primary definition. The dependent variable is in-hospital mortality by day 30, and the independent variables are as described in the print methods. The p-value for the joint test of significance was 0.076, indicating a borderline significant association between the regulations and sepsis mortality using this alternative definition. The table shows the adjusted quarter and group-specific percentages, along with the adjusted estimates and their 95% confidence intervals.

	New York State (% mortality)		**Control States (% mortality)**		
Quarter	**Observed**	**Counterfactual**	**Observed**	**Counterfactual**	**Estimate (95%CI)**
Q1 2013	12.4		10.2		
Q2 2013	11.6	12.3	10.1	10.1	-0.7 (-1.3 to -0.1)
Q3 2013	11.9	12.2	9.9	10.0	-0.3 (-0.9 to 0.3)
Q4 2013	11.6	12.1	9.8	9.8	-0.4 (-1.0 to 0.1)
Q1 2014	11.1	12.0	9.7	9.7	-0.8 (-1.3 to -0.3)
Q2 2014	11.3	11.8	9.5	9.6	-0.5 (-1.2 to 0.2)
Q3 2014	11.3	11.7	9.4	9.5	-0.4 (-1.0 to 0.2)
Q4 2013	10.8	11.6	9.3	9.4	-0.7 (-1.3 to -0.1)
Q1 2015	10.8	11.5	9.0	9.3	-0.5 (-1.1 to 0.2)
Q2 2015	10.4	11.4	9.0	9.1	-0.9 (-1.6 to -0.2)
Q3 2015	10.4	11.3	8.9	9.0	-0.7 (-1.3 to -0.1)
Test of parallel trends[a]					P = 0.28
Model					DID
Joint test of significance					P = 0.08

Q = Quarter; DID = difference-in-differences

[a] Parallel trends in the pre-regulation period were tested using a model containing a treatment indicator, a continuous time variable, the interaction of these two variables, and all patient- and hospital-level covariates, restricting to the pre-regulation period. The reported p-values are from the test of significance of the interaction term from this model. In cases where the interaction term was statistically significantly different from zero, a comparative interrupted time series model was used. Otherwise, parallel temporal trends in the pre-regulation period were assumed and a modified difference-in-differences model was used. These model decisions are outlined in the pre-specified statistical analysis plan.

eTable 13. Sensitivity analysis excluding hospitals that had previously participated in a New York City region-wide sepsis quality improvement initiative

Note: The goal of this analysis was to understand the robustness of the results to exclusion of hospitals that participated in the Greater New York Hospital Association (GNYHA) STOP-sepsis quality improvement initiative (https://www.gnyha.org/topic/stop-sepsis). This initiative was a New York City-wide quality improvement initiative designed to improve sepsis outcomes through education and outreach. This led to the hypothesis that these hospitals may have been high-performing hospitals prior to the implementation of the New York State sepsis regulations, and including them may have led us to underestimate the association between the regulations and sepsis mortality. As in the primary analysis, the dependent variable is in-hospital mortality by day 30, and the independent variables are as described in the print methods. The p-value for the joint test of significance was <0.05, indicating a significant association between the regulations and sepsis mortality even after excluding hospitals in GNYHA. The table shows the adjusted quarter and group-specific percentages, along with the adjusted estimates and their 95% confidence intervals.

	New York State (% mortality)		Control States (% mortality)		
Quarter	**Observed**	**Counterfactual**	**Observed**	**Counterfactual**	**Estimate (95%CI)**
Q1 2013	24.8		20.7		
Q2 2013	22.5	24.8	20.9	20.4	-2.8 (-4.5 to -1.2)
Q3 2013	22.9	24.9	20.4	20.1	-2.4 (-4.3 to -0.5)
Q4 2013	22.1	24.9	19.5	19.7	-2.6 (-4.5 to -0.7)
Q1 2014	22.7	24.9	19.4	19.4	-2.3 (-4.3 to -0.2)
Q2 2014	22.6	24.9	19.4	19.1	-2.7 (-5.3 to 0.0)
Q3 2014	22.0	25.0	19.0	18.7	-3.3 (-5.7 to -0.8)
Q4 2013	22.3	25.0	18.5	18.4	-2.8 (-5.4 to -0.2)
Q1 2015	21.9	25.0	18.1	18.1	-3.1 (-6.5 to 0.2)
Q2 2015	20.2	25.0	18.5	17.8	-5.6 (-9.0 to -2.2)
Q3 2015	20.7	25.1	18.0	17.4	-5.0 (-8.4 to -1.5)
Test of parallel trends[a]					P = 0.001
Model					CITS
Joint test of significance					P = 0.004

Q = Quarter; CITS = comparative interrupted time series

[a] Parallel trends in the pre-regulation period were tested using a model containing a treatment indicator, a continuous time variable, the interaction of these two variables, and all patient- and hospital-level covariates, restricting to the pre-regulation period. The reported p-values are from the test of significance of the interaction term from this model. In cases where the interaction term was statistically significantly different from zero, a comparative interrupted time series model was used. Otherwise, parallel temporal trends in the pre-regulation period was assumed and a modified difference-in-differences model was used. These model decisions are outlined in the pre-specified statistical analysis plan.

eTable 14. Sensitivity analysis shifting the pre-regulation period back by two quarters

Note: The goal of this analysis was to understand the robustness of the results to the primary specification of the timing of the regulations. The New York State sepsis regulations were publicized in New York prior to their implementation (see e**Table 2** for a complete policy timeline). This led to a hypothesis that hospitals may have taken steps to improve sepsis performance prior to the actual enactment of the regulations. The dependent variable is in-hospital mortality by day 30, and the independent variables are as described in the print methods. The p-value for the joint test of significance was <0.05, indicating a significant association between the regulations and sepsis mortality even after moving back the pre-regulation period. The table shows the adjusted quarter and group-specific percentages, along with the adjusted estimates and their 95% confidence intervals.

	New York State (% mortality)		**Control States (% mortality)**		
Quarter	**Observed**	**Counterfactual**	**Observed**	**Counterfactual**	**Estimate (95%CI)**
Q3 2012	24.1		21.6		
Q4 2012	24.5	23.8	22.0	21.2	-0.1 (-1.3 to 1.2)
Q1 2013	25.5	23.4	20.9	20.9	2.1 (0.9 to 3.3)
Q2 2013	22.8	23.1	21.2	20.5	-0.9 (-2.2 to 0.4)
Q3 2013	22.9	22.7	20.7	20.2	-0.3 (-1.6 to 1.0)
Q4 2013	22.2	22.4	20.2	19.9	-0.5 (-2.0 to 0.9)
Q1 2014	22.4	22.0	19.7	19.5	0.2 (-1.1 to 1.5)
Q2 2014	22.3	21.7	19.7	19.2	0.1 (-1.4 to 1.5)
Q3 2014	22.0	21.4	19.3	18.8	0.2 (-1.0 to 1.4)
Q4 2013	21.2	21.0	19.2	18.5	-0.5 (-2.0 to 1.1)
Q1 2015	21.3	20.7	18.3	18.1	0.5 (-0.8 to 1.8)
Q2 2015	20.2	20.3	18.8	17.8	-1.2 (-2.6 to 0.3)
Q3 2015	20.2	20.0	18.3	17.4	-0.6 (-1.8 to 0.5)
Test of parallel trends[a]					P = 0.34
Model					DID
Joint test of significance					P = 0.001

Q = Quarter; DID = difference-in-differences

[a] Parallel trends in the pre-regulation period were tested using a model containing a treatment indicator, a continuous time variable, the interaction of these two variables, and all patient- and hospital-level covariates, restricting to the pre-regulation period. The reported p-values are from the test of significance of the interaction term from this model. In cases where the interaction term was statistically significantly different from zero, a comparative interrupted time series model was used. Otherwise, parallel temporal trends in the pre-regulation period were assumed and a modified difference-in-differences model was used. These model decisions are outlined in the pre-specified statistical analysis plan.

eTable 15. Post hoc sensitivity analysis limiting the control states to those with pre-intervention trends that were most similar to New York.

Note: The goal of this analysis was to understand whether the results were robust to the choice of control states. This analysis was not specified a priori—it was done post hoc after the primary analysis showed significantly different trends in mortality between New York and control states in the pre-regulation period. Although the CITS model did not depend on parallel trends, these differences raised concerns about the comparability of the control states with New York.

As in the primary analysis, the dependent variable is in-hospital mortality by day 30, and the independent variables are as described in the print methods. To perform this analysis, control states with the most markedly different pre-regulation trends were sequentially excluded, which (in order), were Massachusetts, Florida, and New Jersey. In all analyses the point estimates are consistently in the same direction as the primary analysis and within the confidence intervals of the primary analysis. This analysis suggests that the results are robust to choice of control states and the possibility that unmeasured differences between New York and control states drove the findings.

	Primary analysis	**Sensitivity analyses**		
	Controls: MD, NJ, FL, MA	**Controls: MD, NJ, FL**	**Controls: MD, NJ**	**Control: MD**
N (New York)	**325,786**	**325,786**	**325,786**	**325,786**
N (Control)	**686,624**	**582,679**	**250,742**	**108,478**
Year and quarter				
Pre-regulation	--	--	--	--
2013 – Q2	-2.0 (-3.2 to -0.7) P = 0.002	-1.8 (-3.1 to -0.6) P = 0.005	-0.8 (-2.4 to 0.7) P = 0.30	-1.3 (-3.0 to 0.4) P = 0.13
2013 – Q3	-1.4 (-2.8 to 0.0) P = 0.05	-1.4 (-2.8 to 0.1) P = 0.06	-0.7 (-2.5 to 1.1) P = 0.44	-0.1 (-2.3 to 2.2) P = 0.95
2013 – Q4	-1.6 (-2.9 to -0.3) P = 0.02	-1.7 (-3.0 to -0.4) P = 0.01	-1.6 (-3.2 to 0.1) P = 0.06	-1.4 (-3.3 to 0.4) P = 0.13
2014 – Q1	-2.0 (-3.4 to -0.6) P = 0.005	-2.1 (-3.5 to -0.7) P = 0.004	-1.3 (-3.1 to 0.5) P = 0.15	-1.9 (-4.3 to 0.5) P = 0.12
2014 – Q2	-1.8 (-3.6 to 0.0) P = 0.05	-1.7 (-3.5 to 0.1) P = 0.07	-1.2 (-3.5 to 1.1) P = 0.31	-0.9 (-3.3 to 1.5) P = 0.46

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eTable 15 (continued).

	Primary analysis	Sensitivity analyses		
	Controls: MD, NJ, FL, MA	**Controls: MD, NJ, FL**	**Controls: MD, NJ**	**Control: MD**
N (New York)	**325,786**	**325,786**	**325,786**	**325,786**
N (Control)	**686,624**	**582,679**	**250,742**	**108,478**
Year and quarter				
2014 – Q3	-1.6 (-3.3 to 0.1) P = 0.06	-1.5 (-3.2 to 0.2) P = 0.09	-0.7 (-2.9 to 1.5) P = 0.53	-0.7 (-3.6 to 2.2) P = 0.63
2014 – Q4	-2.3 (-3.9 to -0.6) P = 0.008	-2.0 (-3.7 to -0.3) P = 0.03	-1.5 (-3.7 to 0.6) P = 0.16	-2.1 (-5.0 to 0.8) P = 0.15
2015 – Q1	-2.4 (-4.5 to -0.3) P = 0.02	-2.0 (-4.1 to 0.1) P = 0.07	-0.8 (-3.2 to 1.6) P = 0.51	-1.2 (-4.4 to 2.0) P = 0.47
2015 – Q2	-3.7 (-6.0 to -1.5) P = 0.001	-3.2 (-5.5 to -0.9) P = 0.006	-1.7 (-4.3 to 1.0) P = 0.22	-2.2 (-5.4 to 1.1) P = 0.19
2015 – Q3	-3.2 (-5.4 to -1.0) P = 0.004	-2.7 (-4.9 to -0.5) P = 0.02	-1.3 (-3.9 to 1.3) P = 0.32	-2.2 (-5.9 to 1.5) P = 0.25
Test of parallel trends[a]	P = 0.01	P = 0.06	P = 0.75	P = 0.83
Model	CITS	CITS	CITS	CITS
Joint test of significance	P = 0.02	P = 0.05	P = 0.74	P = 0.36
New York record count	325,786	325,786	325,786	325,786
Control record count	686,624	582,679	250,742	108,478

Q = quarter; MD = Maryland; NJ = New Jersey; FL = Florida; MA = Massachusetts; CITS = comparative interrupted time series.

a. Parallel trends in the pre-regulation period were tested using a model containing a treatment indicator, a continuous time variable, the interaction of these two variables, and all patient- and hospital-level covariates, restricting to the pre-regulation period. The reported p-values are from the test of significance of the interaction term from this model. All models used a comparative interrupted time series approach to ensure comparability to the primary analysis.

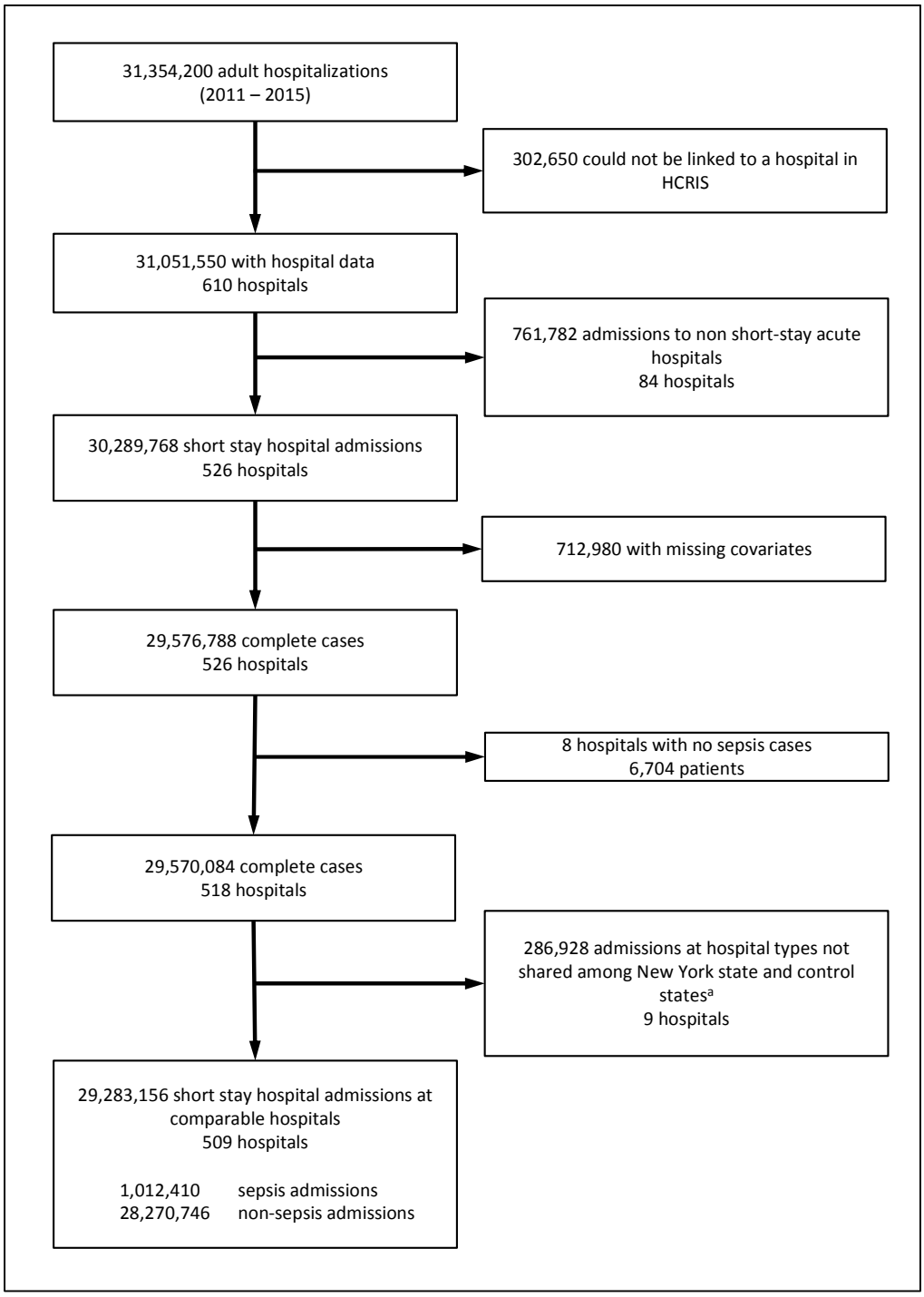
eTable 16. Subgroup analyses for the primary outcome of in-hospital mortality by 30 days.

Subgroup	Total N – Pre-regulation		Total N – Post-regulation		p-value[a]	Tenth quarter estimate [b]
	New York	Control	New York	Control		
Patient						
Age						
≤ 59	31,081	76,003	43,853	106,247	0.12	-0.6 (-2.2 to 0.9)
60-69	26,182	56,723	36,864	81,669		0.7 (-1.1 to 2.5)
70-79	31,150	65,665	42,076	90,840		0.2 (-1.5 to 2.0)
≥ 80	50,606	90,834	63,974	118,643		-1.4 (-2.9 to 0.2)
Comorbidities						
< 3	29,065	45,190	29,974	59,544	1.000	-3.4 (-7.7 to 0.8)
≥ 3	109,954	244,035	156,793	337,855		-3.1 (-5.5 to -0.8)
Organ failures						
< 3	126,853	255,542	168,470	347,024	0.93	-2.4 (-4.6 to -0.2)
≥ 3	12,166	33,683	18,297	50,375		-8.7 (-15.0 to -2.4)
ED use						
No	20,312	32,419	23,701	41,166	1.000	-1.2 (-7.9 to 5.6)
Yes	118,707	256,806	163,066	356,233		-3.5 (-5.8 to -1.1)
Hospital						
Teaching status						
Large	85,978	76,007	118,455	108,278	0.20	-1.2 (-4.2 to 1.9)
Small	27,322	90,439	35,727	125,453		-5.4 (-11.0 to 0.1)
None	25,719	122,779	32,585	163,668		-4.9 (-8.9 to -0.8)
Number of beds						
>250	100,925	186,806	140,769	263,916	1.000	-2.5 (-5.0 to 0.0)
100 to 250	31,413	91,593	37,256	118,102		-3.8 (-8.0 to 0.4)
<100	6,681	10,826	8,742	15,381		-8.7 (-17.5 to 0.2)
Sepsis volume						
≥ 125	96,246	186,939	134,666	262,112	0.09	-2.1 (-4.7 to 0.6)
≥51 and <125	31,044	82,106	39,524	109,605		-5.0 (-8.5 to -1.4)
<51	11,729	20,180	12,577	25,682		-10.0 (-17.6 to -2.4)

[a] The p-value is from a test of whether, across all post-regulation quarters, any of the non-base category subgroup triple interaction terms differ from zero. This joint test of significance is adjusted for multiple comparisons using the Bonferroni correction, where n=7 since there are 7 subgroup analyses. A significant p-value would indicate the presence of variation in the association between the regulations and mortality by subgroup.

[b] Point estimates and 95% confidence intervals for the subgroup-specific estimates for the tenth quarter after the regulation (i.e. July 1, 2015 to September 30, 2015). The p-values represent the joint test for all quarters, but here only the 10^{th} quarter is shown for illustrative purposes. In this context, the 10^{th} quarter is a representative example of the quarter-specific estimates and the one most likely to show a significant association should any subgroup analysis be significant. Although these estimates qualitatively differ by subgroups, in the absence of a significant joint test of interaction, there is insufficient evidence to conclude that the association between the regulations and mortality differed by subgroup.

eFigure. Patient flow diagram.



a. Hospitals in five strata were excluded because there were no hospitals in either New York or control states. The strata containing only control state hospitals were: (a) 100 to 250 beds, large teaching hospitals in a medium metropolitan statistical area (MSA) (3 hospitals); and (b) <100 beds, small teaching hospitals in a large MSA (1 hospital). The strata containing only New York hospitals were: (a) 100 to 250 beds, small teaching hospitals in a small MSA (2 hospitals); (b) <100 beds, small teaching hospitals in a medium MSA (1 hospital); and (c) 100 to 250 beds, large teaching hospitals in a small MSA (2 hospitals).