

# Federalism and the significance of Governmental Agencies and of organizational Experience at the time of country's Crisis: Tracing the Emergency Medication Response System of the Covid-19 Pandemic

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## Abstract

This research has focused on the emergency response based on the section 1135 emergency waivers which were devised as instruments for policymakers to swiftly enhance the capacity of the health system in times of disaster. By providing flexibilities in regulations, administration, and payment models during the COVID-19 pandemic, states could be better prepared for a surge in hospitalizations and protecting the life of those who were in the emergency response to take care through the process of the hospitalization on time. It employs a Time-to-Event analytical framework to identify key factors influencing the adoption of a state's 1135 Waiver request. In the primary model, the event of interest is a state making a request for a Section 1135 Waiver, and the dependent random variable is the time elapsed between the disaster proclamation and the state's request date. The primary independent variable is binary, indicating whether a state has previously sought Section 1135 Medicaid flexibilities during past emergencies. The study stands as the inaugural attempt to pinpoint notable factors influencing Section 1135 Waivers. If efficiency is gauged by swifter requests, then the effectiveness of emergency waivers during the COVID-19 pandemic is predominantly shaped by institutional and external factors. It has revealed that the effective organizational and institutional tasks in the federalism during the emergency would assist to address the issues of the national crisis as it has been explained by the 1135 Waivers as the sample study for further information to the concerned stakeholders not merely in the advanced nation as of the United States of The America but even to the backward countries as of the Asian continents.

**Keywords:** *emergency, covid 19, hospitalization, pandemic, Waiver*

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## Introduction

The federalism has got its own features and models to function the on time in the case of emergency for the protection of the life of the needy and it becomes faster

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in action in quick response to the patients as their critical condition of health. In this respect, the significance of organizational experience at the time of country's crisis can be realized through the tasks that the federal institutions have displayed in the process of tracing the emergency medication system of the Covid-19 Pandemic in the federal country like the United States of America. So, it has focused on the emergency response based on the section 1135 emergency waivers were devised as instruments for policymakers to swiftly enhance the capacity of the health system in times of disaster. By providing flexibilities in regulations, administration, and payment models during the COVID-19 pandemic, states could be better prepared for a surge in hospitalizations. It took one month for every state to adopt a COVID-19 waiver, but no research has explored the reasons behind the variation in the timing of waiver adoption among states. This study employs a Parametric, Time-to-Event design to create a Comprehensive, Institutional, Political, External, and an amalgamated Integrated model to pinpoint the factors influencing the rapid submission of waiver requests.

States with a history of utilizing Section 1135 waivers in previous disasters tended to submit requests to the Centers for Medicare & Medicaid Services (CMS) more promptly than states lacking such experience. In the Integrated Model, four indicators were significantly linked to a shorter time for submitting a request: a prior history of a waiver (0.7248,  $p < 0.01$ ), state health expenditures (0.9994,  $p < 0.001$ ), the presence of a democratic governor (0.6794,  $p < 0.05$ ), and a recent 1135 Waiver request in the region (0.8424,  $p < 0.001$ ). In the context of the U.S. federalist system, states with greater institutional experience and financial capacity appeared to be the most responsive in expanding health system flexibility during the height of the pandemic's uncertainty. The variation among states in their ability to swiftly respond to an emergency may complicate efforts to achieve equity in this pandemic and in the future.

On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS), Alex Azar, declared the COVID-19 pandemic a national public health emergency. This was followed by President Trump's proclamation on March 13th, 2020, officially declaring the COVID-19 outbreak a national emergency (Proclamation No. 9994). These two executive actions, taken together, empowered Secretary Azar to activate the Section 1135 Waiver Authority, thereby immediately providing medical providers nationwide with comprehensive regulatory flexibilities (42 U.S.C. 1320b-5). On the same day, Florida became the first state to initiate additional regulatory flexibilities by submitting a Section 1135 waiver request (CMS 2020). By April 16, all fifty-one states had submitted requests seeking specific flexibilities (Medicaid 2020).

While the Secretary of the Department of Health and Human Services (HHS) has the authority to grant broad waivers across affected regions, once the Section 1135 Waiver authority is activated, states within the specified emergency area can commence making requests for flexibility and capacity tailored to their specific needs (CMS 2017). In recent decades, particularly following the enactment of the Patient Protection and Affordable Care Act (PPACA) in 2010, which further empowered state waiver institutions, the responsibility for requesting waivers has largely fallen on governors and agency directors (Thompson, 2013). Despite state legislatures having enacted statutes that either facilitate or impede a governor's ability to act independently, most state legislatures passively delegate the exclusive authority to request 1135 waivers to the executive branch, allowing governors and agency directors to wield that authority (Hinton, 2019; NCSL 2017).

Emergencies present an immediate threat to health, making it reasonable to assume that, all other factors being equal, a waiver requested more promptly would be more effective. In the case of the COVID-19 emergency, there is a span of thirty-four days between the first and last waiver requests (CMS 2020). However, the question arises: what factors led some states to request waivers sooner than others? Was this variation linked to COVID-19 outcomes, or were there other state-specific elements influencing the timing of these requests? Existing studies propose that financial capacity and political considerations notably impact the use of current waivers (Nattinger, 2016; Nattinger & Kaskie, 2017). Despite this, no study has systematically examined the determinants of the adoption of emergency waivers.

While likely unrelated to the state's COVID-19 situation, this analysis posits that the presence of Section 1135 waiver precedence from previous emergencies significantly influences the timing of a COVID-19 waiver request. Beyond the influence of prior 1135 Waiver experience, this analysis explores whether the timing of COVID-19 waiver requests correlates with contextual factors (such as supply and demand), institutional dynamics, political considerations, or external factors. For instance, did states with a higher proportion of individuals susceptible to COVID-19 hospitalizations tend to promptly request an expansion of hospital capacity? Alternatively, were 1135 Waiver decisions influenced by the state's supply of hospitals? Furthermore, after accounting for contextual factors, how do the capacities of state agencies, legislative bodies, and the executive branch affect the time it takes to adopt 1135 Waivers? Additionally, does state ideology play a role in the negotiations surrounding emergency waiver decisions?

The COVID-19 pandemic has underscored for policymakers that national disasters

do not affect states uniformly. Since 1135 Waivers were created to offer states flexibility in addressing their context-specific needs, it is preferable for emergency waiver activity during COVID-19 to be guided by each state's requirements in the initial month of the pandemic. However, if factors unrelated to need are influencing the timing of 1135 Waivers, existing disparities could be exacerbated without additional intervention due to inherent differences among states.

## Method

This study employs a Time-to-Event analytical framework to identify key factors influencing the adoption of a state's 1135 Waiver request. Time-to-Event analyses, traditionally utilized by public health researchers to model survival (Lee & Go, 1997), can more broadly be applied to any event that is influenced by the duration from its onset (Schober & Vetter, 2018). In the primary model, the event of interest is a state making a request for a Section 1135 Waiver, and the dependent random variable is the time elapsed between the disaster proclamation and the state's request date. The primary independent variable is binary, indicating whether a state has previously sought Section 1135 Medicaid flexibilities during past emergencies.

Policy analyses involving time-to-event scenarios can be approached using various methods, each offering different levels of interpretability and complexity. To bolster the robustness of this study, three distinct approaches are employed: Kaplan-Meier, Cox Proportional Hazard, and Parametric (Gamma).

The Kaplan-Meier analysis, regarded as the most general, is a non-parametric model that assesses the time to survival between two distinct groups (Dudley 2016). Being a non-parametric model, the Kaplan-Meier estimate remains insensitive to the underlying distribution of a state's time to request. This Kaplan-Meier model compares the timing of COVID-19 waiver requests between states with and without 1135 waiver precedent from previous emergencies. However, it's important to note that this Kaplan-Meier estimate cannot account for any other covariates influencing a state's timing to make a request (Rich 2010).

To incorporate additional variables that might uncover factors influencing the timing of a state's request, two alternative approaches are employed: a Cox Proportional Hazard Function and a Parametric Model. In a Cox Proportional Hazards analysis, the "risk" of requesting a waiver at any given time (conditional on not having already requested a waiver) is estimated. Conversely, the parametric model assesses the impact of each variable on the duration until a waiver request. In addition to interpretability, this parametric model offers advantages over the Kaplan-Meier

and Cox methods. While parametric models are typically not favored due to additional assumptions related to the chosen distribution (Abadi 2012; Siannis 2005), a Generalized Gamma incorporates multiple distributions, providing the greatest flexibility with minimal assumptions (Cox 2007; Cox & Matheson, 2014; Matheson 2017). Another benefit of the parametric model is the inclusion of robust standard errors, which can accommodate potential heteroskedasticity in the model (Yau, 2001; Gutierrez, 2002).

Following a framework established by previous time-to-event studies, the Gamma analysis fits a Contextual, Institutional, Political, External, and a combined Integrated model (Berry, 1990; Nelson, 2007; Eaton, 2013). As a sensitivity analysis, Cox model estimates will be reported, along with a test of the assumption that risks do not differentially vary over time for each model.

The information regarding the request dates for Section 1135 Waivers in each state was acquired from CMS communications with state Medicaid Directors. Prior 1135 Waiver activities were gathered through a systematic approach: 1) identifying past public health emergencies for all states (DHHS, 2020), 2) determining which public health emergencies prompted the activation of Section 1135 Waiver authority (DHHS, 2020), and 3) examining archival correspondences (CMS, 2020; PHE, 2019; ASTHO, 2010) and reports from the federal government (81 FR 63859).

Building on insights from prior research on policy determinants (Imhof & Kaskie, 2008; Nattinger, 2016; Nattinger & Kaskie, 2017), the conceptual framework of this study advocates for the incorporation of state indicators related to the supply and demand of COVID-19 care (contextual factors), institutional factors encompassing administrative, executive, and legislative capacity to respond to a pandemic, and political factors such as state ideology. Furthermore, the study integrates state and regional indicators to conceptualize external factors that might have influenced when and how a state requested a Section 1135 Waiver.

The demand for COVID-19 response in a state was measured by the percentage of the population over the age of 65, the percentage of the population with multiple comorbidities, and the percentage of the population covered by Medicaid insurance (Jordan, 2020). Considering the intensive care required for COVID-19 patients, state supply factors encompassed hospitals per capita and Intensive Care Unit (ICU) beds per capita (Hancock, 2020; Waldman, 2020). State Medicaid agency capacity was operationalized using recent state expenditure data, including Medicaid, hospitals, and total healthcare spending, and the presence of a current Section 1135 Medicaid Waiver (Jordan, 2020; Hinton, 2019). Legislative and executive

capacity were measured using salary and staff expenditure data, with the Executive model additionally incorporating features such as “Line-Item Veto” and additional public health emergency authority (Jordan, 2020; Perkins, 2019). State ideology was captured through the current Governor’s political affiliation, the percentage of Democrats in the current state senate, and the estimated percentage of citizens with “liberal views” (Jordan, 2020; NCSL, 2019; NGA, 2020).

Lastly, in addition to COVID-19 cases and deaths at the time of the requested waiver, the external model included a binary variable indicating if a new 1135 Waiver was requested in the region, with regions determined by state networks (Olsen, 2019).

## Results

### Unadjusted, Cox, and Parametric Models

States that had Section 1135 precedent from previous disasters tended to submit requests to CMS more rapidly compared to states without prior experience, although these differences showed only marginal significance (refer to Figure 1). As depicted in Figure 1, states with at least one previous 1135 Waiver experience tended to request a COVID-19 waiver more promptly ( $p = 0.1023$ ). Furthermore, states with two or more prior 1135 experiences exhibited a quicker request for a COVID-19 waiver compared to states with one or fewer previous 1135 waiver experiences (see Figure 2,  $p = 0.0500$ ). In the unadjusted model (see Table 1), the Cox Proportional Hazard for states with 1135 precedent indicated a higher likelihood of requesting a COVID-19 waiver at any given time (Hazard Ratio 1.5605), although this effect did not reach statistical significance compared to states without precedent. However, in the parametric model, the time-to-waiver request was (marginally) significantly shorter for states with previous 1135 Waiver experience (Time Ratio = 0.7522).

### Integrated Model

As anticipated, the Full Integrated Model demonstrated the most optimal fit ( $p < 0.0001$ ). Within this comprehensive model, four indicators exhibited a statistically significant association with a shorter time to request: a history of a previous waiver (0.7248,  $p < 0.01$ ), state health expenditures (0.9994,  $p < 0.001$ ), a democratic governor (0.6794,  $p < 0.05$ ), and a new 1135 Waiver request in the region (0.8424,  $p < 0.001$ ). The only variable displaying a statistically significant association with a longer time-to-request was COVID-19 cases (1.0230,  $p < 0.001$ ). Table 2 presents the complete estimates from each model, detailing their impact on time-to-waiver request, along with the results of the Cox Proportional Hazards analysis as a sensitivity check.

## Discussion

The ongoing severity of this disaster necessitates sustained attention from policymakers across all levels of government. While Section 1135 Waivers constitute only a portion of the overall COVID-19 response, they offer states a distinctive opportunity to reallocate healthcare resources and enhance health system capacity. Nevertheless, this research underscores that states have adopted varied approaches even within the framework of Section 1135 Waiver authority. In essence, the timing of a state's response is associated with institutional factors (such as 1135 Waiver experience and state agency capacity) and external factors (the emergence of a new 1135 Waiver in the region). These inherent disparities among states in determining the timing of 1135 policies pose challenges. However, this newly presented evidence should encourage ongoing innovation by state and local policymakers. As states continue to submit second and third 1135 Waivers for COVID-19 (CMS 2020), the public can anticipate more prompt requests.

## Federalism and COVID-19

The architects of the U.S. Constitution, although not explicitly using the term “emergency,” recognized the advantages and drawbacks of establishing centralized authority during national emergencies (Hamilton, 1787). Concerned about the potential for unchecked presidential authority leading to tyranny, emergency powers were intentionally not delegated to the executive branch (Hamilton and Madison, 1788). Instead, Article 1, Section 8 of the U.S. Constitution vests Congress with the authority to declare war, mobilize an army in times of war, and maintain an army during times of peace. Importantly, the framers foresaw the extension of these powers to unforeseeable situations in 1788, including disasters during times of peace (Madison, 1788). Despite the risks associated with concentrated emergency power in the Executive branch, the framers acknowledged its value in responding promptly and effectively to emergencies, leading to broadly interpreted and largely undefined executive authority during such situations (Fisch, 1990). As presidents began utilizing emergency proclamations and executive orders, the federal Judiciary responded with oversight powers to prevent presidential overreach, as seen in cases like *Ex parte Merryman* (1861) and *Youngstown Sheet & Tube Co. v. Sawyer* (1952).

In the twentieth century, there was a notable shift in the constitutionally prescribed allocation of emergency powers. Towards the end of World War II, Congress enacted the Public Health Services Act (42 U.S.C. cha. 6A § 201), with section 319 granting the Health and Human Services (HHS) Secretary the authority to declare a national public health emergency (42 U.S.C. 247d). This shift of emergency power from

Congress to the President continued with two subsequent statutes: The National Emergency Act of 1976 (50 U.S.C. §§ 1601-51) and the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 (42 U.S.C. §§ 5121-5207). Both acts explicitly confer the authority to declare a national emergency to the President. When both a public health and national emergency are declared, the HHS Secretary can invoke Section 1135 Waiver Authority, granting regulatory flexibilities to providers and hospitals in the designated emergency areas (42 U.S.C. 1320b-5). However, despite limited precedent, similar to cases addressing executive overreach during wartime, the Judiciary retains the authority to ensure that both the President and Secretary operate within their delegated emergency powers (*PHN v. U.S.* 2015).

Modern analysis proposes two overarching approaches to comprehend federalism. The first delves into the shifting power dynamics within each branch and level of government, while the second explores the inclination toward cooperation (Rigby & Haselswerdt, 2013; Weil, 2013) or competition (Shannon & Kee, 1989; Volden, 2005; Weil, 2009) among jurisdictions. The findings of this study offer insights for both approaches. In contrast to other Medicaid Waivers, which are primarily steered by state executives and agency directors (Weissert & Scheller, 2008; Weissert & Weissert, 2017), Section 1135 Waivers allocate more authority to the federal executive branch. Even following 1135 invocation, requiring two federal actions, the HHS Secretary promptly provides a set of “blanket” flexibilities for all states, minimizing the need for subsequent requests. State power is also diminished from the “bottom-up,” as local or municipal governments and health systems can bypass state authority to request their own waiver. However, this diminished authority does not universally apply to the COVID-19 pandemic, which has witnessed a substantial expansion of the role of state executives (Cook, 2020). Of particular interest is the evident diffusion among states. The adoption of concurrent waivers with other states in each region in the 1135 Waiver diffusion aligns with other cooperative activities necessary for states to pool resources, suggesting that Section 1135 Waiver experience and expertise may be a valuable resource for neighboring states.

### **Conclusion**

This study stands as the inaugural attempt to pinpoint notable factors influencing Section 1135 Waivers. If efficiency is gauged by swifter requests, then the effectiveness of emergency waivers during the COVID-19 pandemic is predominantly shaped by institutional and external factors. In contrast, the timing of emergency waiver decisions does not seem to be propelled by supply and demand. These results should encourage additional research delving into the consequences of delayed adoption on COVID-19 outcomes. More crucially, they should guide

immediate policy decisions as state policymakers persist in navigating the ongoing pandemic. This has revealed that the effective organizational and institutional tasks in the federalism during the emergency would assist to address the issues of the national crisis as it has been explained by the 1135 Waivers as the sample study for further information to the concerned stakeholders not merely in the advanced nation as of the United States of The America but even to the backward countries as of the Asian continents.

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