



Rapid



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# Review

## Waivers to Enable Innovation in Care Delivery

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# Introduction and Background

Around the world, health systems face the challenge of meeting the needs of growing populations who are living longer often with complex chronic conditions. This long-term population trend combined with rising health care costs are forcing health system leaders, planners, and managers to find innovative and cost-effective ways to support the changing needs of people in a variety of settings. Some jurisdictions, like the United States (U.S.) and France, are using regulatory permissiveness as a way to offer time-limited leniency from statutory or regulatory requirements to implement innovative programs and delivery models. Others, like the United Kingdom (U.K.), have enabled innovation by delegating budgetary and planning authority to local governments.

This report examines the experiences of the U.S., U.K. and France with respect to the use of regulatory waivers or administrative agreements. The U.S. has used waivers since the formation of its Medicare and Medicaid programs in the 1960s to allow for local experimentation and deviation from statutory and regulatory restrictions. In the U.K. and France, the experience with devolution and waivers to enable experimentation and innovation is more recent.

These international experiences may provide useful lessons and considerations for other jurisdictions, such as in Ontario where major system changes are underway to better meet the long-term health and social care needs of its population. This report summarizes the experience of regulatory permissiveness in the U.S., U.K. and France that aimed to achieve innovation in care delivery and draws some lessons for the Ontario context.

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## Methods

The scope of this rapid review is limited to the availability of experts internationally who have observed and studied regulatory permissiveness. This review was completed in four weeks and is therefore not a robust discussion of all existing models of regulatory permissiveness deployed to support innovative care delivery.

In order to complete this review, we contacted local experts in the following jurisdictions: New Zealand, Australia, Germany, the U.K., the U.S., and the Netherlands. Among those who responded, some (e.g., New Zealand) suggested that the concept of regulatory permissiveness was not relevant to their jurisdictions, while others (e.g., Germany) were unable to participate given the time constraints.

We requested that our experts use a template to guide data collection if they believed their jurisdictions were engaging in some form of regulatory permissiveness to support the development of innovative interventions. These jurisdictions included the U.S., the U.K., and France. The templates requested information about national/provincial/state/regional laws that might be in place that would require formalized “waiving” in order to implement flexible and innovative programs. Specifically, these templates included the following questions:

1. Do you have a program that allows for regulatory or statutory permissiveness in order to overcome legislative or regulatory barriers that may otherwise block attempts to innovate?
2. What is the objective of the program?
3. What types of reforms is the program supporting?
4. How are these innovations approved?
5. Do these innovations, once approved, receive any dedicated funding?
6. Is there a time limit on the innovation?
7. Is there a formalized evaluation component or dedicated reporting features?
8. Have there been any formalized evaluations of the program overall?

We asked experts from the U.S., the U.K., and France to answer these questions through the use of publicly available documents and consultations with experts. This report describes these three contexts in detail, and then highlights specific examples within each. It concludes with a summary of some of their benefits and drawbacks and the relevance of such initiatives to Ontario’s current context.

# Analytic Overview

## United States

The U.S. health insurance system consists of a complex mix of privately financed, public, and publicly subsidized coverage (Camillo, 2016). Employer-sponsored insurance (ESI) was the most common form, but has been increasingly supplemented in piecemeal fashion by public programs and publicly supported non-group products as the private market began to effectively price out segments of the population.<sup>1</sup> In 2017, 56% of Americans had ESI, 16% had direct-purchase individual insurance, and 37% were insured by one of the three major public programs—Medicare, a national social insurance program for seniors and disabled individuals; Medicaid, a means-tested federal-state program for certain categories of low-income individuals; and the Children's Health Insurance Program (CHIP), a means-tested federal-state program for low-income children—while an additional 9% of Americans were uninsured (Berchick, Hood, & Barnett, 2018).<sup>2,3</sup> Medicare and Medicaid are expected to continue to grow relative to private insurance due, respectively, to the aging of the baby boomer generation and citizens' demands for affordable coverage alternatives (Sisko et al., 2019).

Prior to the enactment of comprehensive health reform via the thousand-page Patient Protection and Affordable Care Act (ACA) of 2010, no overarching principles were in place to regulate the health insurance system. Instead, "U.S. governments relied on the microregulation of health care provision" (Maioni, 1998). As a result, each form of insurance is regulated separately and has distinct financing, payment, and care delivery mechanisms.

In recent decades, as policymakers have sought to expand coverage, reduce health costs, improve the quality of care, change consumer behavior, and accomplish other varied political and ideological objectives, they have provided increased flexibility to health insurers—particularly those receiving public funds—to implement alternative financing, payment, and delivery models through a variety of "waivers."

## Private Health Insurance

Consistent with their prerogative to regulate and tax insurance more generally, states mostly regulate private group and individual health insurance. In 1912, the National Convention of Insurance Commissioners developed model legislation to assist states with health insurance regulation (Kaiser Family Foundation, 2011) and since then regulatory activities have expanded over time, most notably after the rapid spread of managed care in the 1990s and more recently with the passage of the ACA. State responsibilities include licensing, solvency and rate review, consumer protection, running health insurance marketplaces, or partnering with the federal Health Insurance Marketplace, to assist individuals and small businesses with purchasing both subsidized and unsubsidized qualified health coverage.

<sup>1</sup> In 2016, the U.S. spent nearly twice as much of its gross domestic product (GDP) on health care as 10 other high-income countries, including Canada (Papanicolas, Woskie, & Jha, 2018). The U.S. also spends much more per capita (Sawyer & Cox, 2018). In 2018, the average annual premiums for ESI for single and family coverage increased by over 3% to \$6,896 and \$19,616 respectively. The average family premium has increased 55% since 2008.

<sup>2</sup> Many Americans had multiple types of coverage, both private and public, and public and public.

<sup>3</sup> Other sources of coverage included military health care for active duty troops, veterans, and their families and Indian Health Service (IHS) benefits for federally recognized American Indians and Alaskan Natives.

In legislating state marketplace requirements and providing for federal subsidization, through premium tax credits and cost-sharing reductions, of marketplace coverage purchased by eligible low-income families, the ACA expanded the federal role in private health insurance. A Center for Consumer Innovation & Insurance Oversight (CCIIO) was established at the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services, to implement these provisions. The CCIIO has authority under section 1332 of the ACA to grant waivers (known as State Innovation Waivers or State Relief and Empowerment Waivers) of certain ACA provisions to states to test innovative strategies for providing residents with access to high-quality, affordable health insurance while not necessarily adhering to all statutory provisions. In granting these waivers, CCIIO may allow states to redirect the federal subsidies their residents would otherwise receive. However, waivers must be federal deficit neutral. To date, CMS has granted eight states section 1332 waivers. New Jersey's waiver, for example, allows it to have more than one risk pool so that it can implement a reinsurance program (Centers for Medicare & Medicaid Services, 2018a). All waivers been approved for five-year periods and are renewable.

## Medicare

Medicare was enacted in 1965 when the U.S. Congress added a health insurance program for aged persons (seniors, or individuals over 65) at title XVIII of the federal Social Security Act to complement retirement, survivors, and disability insurance benefits already provided under other titles. In 1973, Congress expanded eligibility to certain disabled individuals and individuals with end-stage renal disease. The program currently covers 60 million, or roughly 18% of Americans (CMS, 2019a).

Under Medicare Part A Hospital Insurance, all beneficiaries receive inpatient hospital, home health agency, and some skilled nursing, and hospice benefits. Under Part B Supplementary Medical Insurance, beneficiaries may receive physician and certain covered outpatient services upon payment of premiums, deductibles, and coinsurance. Under Part D Prescription Drug Coverage, beneficiaries may receive subsidized or unsubsidized prescription drug benefits depending upon their income level. For all parts, beneficiaries can elect to receive benefits through traditional fee-for-service (FFS) mechanisms or private insurance (Medicare Advantage) plans that contract with the federal government. Nearly all U.S. hospitals and physicians participate with the Medicare program. They are paid according to complex inpatient and outpatient prospective payment systems and fee schedules that are updated annually. Medicare Advantage plans are paid pre-negotiated, risk-adjusted rates per capita.

The CMS is responsible for administering Medicare. Among its responsibilities, it enrolls providers, determines which services to cover, updates payment methodologies, adjudicates appeals, oversees claims processing, and pays claims. It carries out program changes, including the list/delisting of services, through the formal rulemaking process laid out under the federal Administrative Procedure Act (APA), which requires formal issuance of proposed and final rules in the Federal Register, public participation, and the publication of final regulations in chapter 42 of the Code of Federal Regulations (CFR). The CMS also issues sub-regulatory guidance through a variety of channels, including via updates to program manuals.

As specifically directed by Congress and/or in accordance with the discretionary authority to undertake demonstration projects provided under section 1115A of the Social Security Act, the CMS tests and evaluates innovative, alternative models for delivering and paying for Medicare services for purposes that include improving care coordination, enhancing provider performance, and reducing costs.

Demonstrations could entail a "waiver" of a provision of the Medicare statute or regulations. While these demonstrations were previously conducted by designated units within the CMS, the ACA established a CMS Innovation Center to lead them, thus increasing their profile and resource allocation. Current Innovation Center projects include the Next Generation Accountable Care Organization model, the Comprehensive Care for Joint Replacement Model, and the Emergency Triage, Triage, and Transport Model. Other projects focus on aligning care for so-called "dual eligibles," individuals who are eligible to receive both Medicare and Medicaid benefits by virtue of being aged or disabled and, thus, are typically costlier to insure. The Innovation Center recruits demonstration project participants through a competitive process, commonly offering health care providers incentives to participate.

As a national, centrally run program, Medicare generally does not make state-level policy decisions or grant waivers of policy or procedure based on geographic jurisdiction. However, in an unusual circumstance, language codified in Section 3 of the ACA, allows Maryland to set its own rates for hospital services (CMS, 2018b). The Maryland Health Services Cost Review Commission uses this waiver to establish per capita hospital rates as a way of managing hospital performance.

## Medicaid/CHIP

The Medicaid (formally Medical Assistance) program was enacted via the same 1965 legislation as the Medicare program, but with a different intention and design—namely, to assist participating states with providing health insurance coverage to certain low-income individuals and families across the entire state. Under title XIX of the Social Security Act, states that furnish medical assistance to eligible individuals per federal requirements receive quarterly matching payments from the U.S. Treasury. As of 1982, every state operates a Medicaid program.

The Children's Health Insurance Program (CHIP) was added to the Social Security Act in 1997 to permit federal funding to states to provide health insurance coverage to low-income children with family income that exceeds Medicaid standards. States could choose to do so by expanding Medicaid or creating separate CHIP programs. All states currently run CHIP programs. Total national Medicaid/CHIP enrollment exceeds 72 million individuals or 22% of the U.S. population (CMS, 2019b).

Hundreds of federal requirements pertaining to program administration and monitoring, eligibility standards and processes, benefit coverage, care delivery, and provider payments are enumerated in the Medicaid and CHIP statutes, often with great specificity. For example, states can provide Medicaid to so-called "childless adults" with income up to, but not exceeding, 138% of the official Federal Poverty Level. In addition to these federal requirements, hundreds more state options are provided. Among them, for instance, states may choose to impose nominal cost sharing on certain beneficiaries for certain non-emergency services.

The federal requirements and options are spelled out in greater detail in chapter 42 of the CFR, following rulemaking processes that typically include extensive consultation with states and their representative organizations, such as the National Association of Medicaid Directors. The requirements and options are often further elaborated upon in "plain English" in sub-regulatory guidance issued by the Secretary of Health and Human Services or a CMS designee in forms such as "State Medicaid Director Letters," "Frequently Asked Questions," or "Informational Bulletins." This sub-regulatory guidance is often released

before rulemaking is complete in order to give states policy direction, but it does not carry the same force of law.

As a condition of federal financial participation, each state Medicaid/CHIP program must be officially documented in a “state plan” that services as a contract between the state and the federal government. States make changes to their programs through formal “state plan amendments.” Depending upon the state request, CMS’ review may be perfunctory or may result in requests for clarification and additional information to ensure that the state will faithfully implement the specific statutory/regulatory provision in question.

The Social Security Act provides the federal government with various statutory “waiver” authorities to allow states to receive federal matching funds for expenditures that would otherwise not be in compliance with federal requirements. The most commonly used waiver authorities are section 1115, section 1915(b), and section 1915(c). Each was developed for a different purpose, has a separate application and approval process, and is ostensibly time-limited.

Section 1115 authority allows the Secretary of Health and Human Services to waive compliance with specific statutory requirements or to permit expenditures that are not otherwise matchable for the purposes of demonstrating different approaches to meeting program objectives. Section 1115 waivers include an evaluation requirement and must be budget neutral. They are approved for five years and can be renewed for three- to five-year periods, although it should be noted that Arizona has operated its program using the section 1115 waiver authority since 1982. Early section 1115 waivers tested different approaches for moving Medicaid families off of welfare by allowing them to retain coverage while working. Until the 1990s, most waivers were small in scope and focused on specific populations.

More recently, the use of section 1115 waivers has been broader in focus targeting health system reforms and particularly prioritizing reforms of the delivery system. A notable example is Vermont's Global Commitment to Health waiver, which converted the state's Medicaid program into a public-managed care organization. In the post-welfare reform era, section 1115 waivers have proliferated. In January 2019, 38 states were operating 46 different section 1115 waivers and an estimated 20 states had a total of 22 pending.

Section 1915(b) waiver authority permits the Secretary to waive state compliance with “freedom of choice” and “statewideness” requirements so that it can operate mandatory managed care programs (as opposed to traditional FFS programs) in all or some portions of a state, require that all beneficiaries participate in them, and use the savings to provide services not covered under the statute. Section 1915(b) waivers are approved for a two-year period. They differ from state plan authorities that permit states to deliver services through managed care organizations (MCOs) in that they allow states to require all beneficiaries to enroll in MCOs.

Section 1915(c) home and community-based services waivers allow the Secretary to authorize federal expenditures for special, targeted home and community-based services to particular groups of individuals, with an institutional level of care, such as children with autism, who would otherwise only be eligible for Medicaid if institutionalized. Nearly all states operate 1915(c) waivers with some operating 10 or more. They must be renewed periodically.

## UK (England)

The U.K. has a government-sponsored universal health care system called the National Health Service (NHS). The NHS consists of four publicly funded health care systems in the UK, and our focus is on England. The Department of Health steers the system through regulation but there have been discussions and steps taken to shift away from the department's role toward independent regulators. This trend is consistent with an ongoing devolution process, which aims to increase local accountability for the organization and delivery of care and services, and to adapt care to local needs (The King's Fund, 2015). At this time, the English regulatory regime does not issue formal exemptions or waivers from general rules to support innovative initiatives.

Although there is no equivalent legislative mechanism in the U.K. comparable to the waivers used in the U.S., innovations are enabled through administrative provisions—notably with respect to delegation and reorganisation. These can be undertaken without either primary legislation (acts of parliament) or secondary legislative provisions (statutory instruments passed by parliament that enact or provide for the implementation of the primary legislation).

This approach to enable innovation through administrative delegation appears to have both advantages and disadvantages. On the one hand, innovations could be implemented using administrative provisions without changing overarching statutes, while on the other, these provisions can be limiting when substantial changes in the organization and delivery of care are required. A commonly cited example of this type of administrative delegation to foster innovation in England is the Greater Manchester (GM) model.

### The Greater Manchester (GM) Health and Social Care Partnership

In 2015, the central government devolved a health and social care budget to the GM local government, for its 2.8 million residents to improve health outcomes and reduce health inequalities, and to address a gap between need and demand for health and social care and available resources to provide them (Walshe et al., 2018). The Greater Manchester Health and Social Care Partnership (GM Partnership) was established, which brought together, based on administrative agreements, NHS organisations, local authorities and stakeholders in health and social care in Greater Manchester. This partnership also included the establishment of 10 local care organisations (LCOs) to date, which are local adaptations of Accountable Care Organisations; these had not yet fully been established as of December 2018. Moreover, there are plans to restructure the acute care system to reduce variation in care by creating a “single shared service” model for acute and specialized care by 2021. A recent evaluation noted the considerable investments made to build relationships among the health organizations and to develop shared governance arrangements, but that the process of devolution is still in transition (Walshe et al., 2018). Moreover, the authors suggested that administrative delegation may not be sufficient to promote integration, and that “devolution in Greater Manchester will need some continuing support from central government including access to resources and some relief from national performance regimes and accountability requirements, and some further devolved powers.”<sup>4</sup>

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<sup>4</sup> Walshe et al., (2018), p. 53

## France

The French health care system is characterized by an almost single public payer, the increasing importance of tax-based revenue for financing health care and strong state intervention. State health insurance is financed by employer, employee and retiree contributions, but is increasingly substituted by income taxes. Providers of outpatient care are mostly private, while hospital beds are found in a mix of public and private (for-profit and non-profit) hospitals.

In the context of rising health care costs, the state is increasingly steering the system through regulation. This involves extensive negotiations among the ministries of health, budget and public accounts, and statutory health insurance fund and provider representatives (hospitals and health professionals). Since 2003, France has supported the implementation of experimental innovations by providing financial incentives and a mechanism of dispensation that allows for an exemption from a law (allowed by constitutional law). Such experiments, or pilot programs, have been practiced in France for the past 15 years, however there has been no common framework or dedicated funding for innovative programs in the health sector. Each pilot program requires a law explaining the need for dispensation and justification for the amount of funding.

The government passed Article 51 of the Social Security Financing Law (2018), as a new regulatory framework for implementing and financing experiments in the health sector. The aim of this new regulatory framework is to encourage greater use of pilot programs to improve patient experience, access and pathways to care and services, and overall efficiency of health and social care services (Ministère des Solidarités et de la Santé, 2019). The law also provides a consolidated budget for all the pilot programs in the health sector via a health system innovation fund (Fonds d'innovation du système de santé [FISS]) endowed with €20 million in 2019.

The principle contribution of Article 51 to health care delivery innovations is that it simplifies the legal process for initiating a pilot project and streamlines the financial support by consolidating funding. Regional health agencies, established in 2010, act as intermediary actors supporting innovation at a regional level, and maintain local decision-making power, including with regard to the disbursement of the innovation fund (although rules for funding disbursement are provided by the ministry) and the related regional intervention fund. Article 51 targets large-scale innovations with a broad scope of programs at local, regional, interregional or national, in health care, prevention, and medico-social or social sectors with a maximum duration of five years. Dedicated funding aims to support pilot projects testing new payment methods in revised and/or newly established pathways and processes of care and services (e.g., to enable multidisciplinary care).

It is expected that Article 51 will not only facilitate structural transformations in the delivery of care, but will also facilitate a paradigm shift across the entire health and social protection system to act as a holistic and integrated care system.<sup>5</sup> The regulatory framework is designed with a bottom-up approach in mind to foster participation and to reflect the needs and interests of the users in the system. In the same vein, it also aims to foster an entrepreneurial climate to support innovations by relaxing eligibility requirements for funding. An egalitarian approach is practiced and applicants can include a variety of users' associations,

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<sup>5</sup> L'article 51: Comme un nouveau départ?: [https://observia-group.com/images/Compte-rendu\\_Carrefour\\_de\\_lObservance\\_6ème\\_édition\\_VF.pdf](https://observia-group.com/images/Compte-rendu_Carrefour_de_lObservance_6ème_édition_VF.pdf)

a health institution (public or private), hospital federations, professional unions, health care professionals, home care professionals, insurance organizations or local authorities. Since 2012, systematic evaluation of experimental projects is required by the law. These evaluations are to be conducted no later than one year upon completion of the pilot. Two of the early pilot programs that have since been scaled up are described below.

### Elderly at risk of losing autonomy (Personnes âgées en risque de perte d'autonomie–PAERPA)

This pilot program aimed to improve the coordination and quality of care for people 75 and older to prevent their loss of autonomy and reduce their hospital use (Commonwealth Fund, 2018). The PAERPA program was implemented in 2014 with a special dispensation of Article 48 of the Social Security Financing Law (2013) on an experimental basis in nine regions. PAERPA dispensation as prescribed in the terms of reference superseded regulations that were in force at the time of its implementation, and which required regional health agencies to bring together different local stakeholders and sectors, including public health, social care and medical care to support new pathways for the care of the elderly.

Each region negotiated with local entities, including local health insurance organizations, regional unions of health professionals (URPS), health and medico-social institutions, and the general council of the ministry of health to implement the experiments in accordance with Article 48. At the national level, funding for PAERPA was provided by Social Security Financing Law (2013) and then allocated to regional intervention funds (FIR) which, in turn, allocated an annual flat-rate payment to the regional health agencies. These funds covered support functions (e.g., expenditure on governance and dedicated territorial coordination), payments to frontline professionals (e.g., additional fees for personalized health plans), the costs incurred by the reorganization of health and social care facilities, and information sharing capacities (e.g., support for the use of a secured information system). An interim evaluation suggested that there were some improvements in polypharmacy and emergency visits but no impact on hospital utilization to date (Or et al., 2018).

### Experimentation in new methods of remuneration (Expérimentations de nouveaux modes de rémunération–ENMR)

The ENMR program is an “add-on” or “top-up” payment scheme introduced in France in 2009 via the Social Security Financing Law (2008) to co-finance the operation of health centers during the period 2009-2013. They were subsequently extended until the end of 2014. In 2015, the ENMR program was generalized in scope to cover new multidisciplinary settings. Initially, add-on payments were directed to the organizations providing care (primary care organizations at first), and not to the professionals directly; these payments aimed to support coordination of care, the provision of new services and inter-professional collaboration. The ENMR payments made up an average of 5% of the health care organization’s revenue. Participants in the program were selected by regional health agencies. Take up varied but gradually increased over the years to total some 300 organizations in 2014. An early evaluation of this model found positive impacts in terms of maintaining or increasing the supply of GPs in more disadvantaged areas, and some improvement in efficiency measures, but with no change in hospital care (Mousques et al., 2014).

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## Relevance to Ontario

This review revealed three broad approaches taken to enable innovation in care delivery:

1. The highly legalistic statutory approach in the U.S.
2. The administration delegation to local government in England
3. The reform-oriented waivers with the specific purpose of encouraging innovation in France

These approaches provide some lessons for Ontario, as each provide opportunities for enabling innovation in care delivery, as well as some considerations based on the experiences and challenges faced in these three countries. Table 1 summarizes a selection of innovative care delivery models using waivers or administrative delegation that may be relevant to Ontario. Overall, there are some general elements that may play a role in supporting implementation and their positive impacts on care processes and outcomes:

- A structured and formalized approach for approval and selection
- A time-limited approach to the program to allow for experimentation
- Incorporate and support rigorous evaluation
- Ability to renew and/or scale up when there is evidence of positive impact
- Ongoing engagement and supporting relationship development across care sectors

In the U.S., waiver processes have given the federal government an open and formal means for encouraging innovation in state health systems that can be driven below the political level (i.e., largely carried out by public servants with technical expertise). Due to their formal mechanisms, waivers, particularly 1115 and 1915(c), have been used successfully to engage health care providers in reforms that they might otherwise remain disengaged from (despite their best intentions or pledges to participate). Waiver authority, particularly section 1115, has been successful in allowing the Medicaid program to adapt to changes in health care, such as the transition from FFS to managed care, by phasing them in over time in such a way that the public/beneficiaries/taxpayers remain relatively protected. Waivers allowed states with significant diversity, such as New York (with its huge metropolis and rural Appalachian counties), to meet the varying needs of its communities by providing for different methods of delivering health care.

Waivers have been a successful instrument of federalism in the U.S. by allowing leading-edge states (e.g., Vermont, Massachusetts, New York and Hawaii) to experiment while not forcing others (e.g., Wyoming) to implement similar sweeping changes. Waiver authorities, again particularly the 1115, have provided a formal public mechanism for spreading pilot projects that have been evaluated to a degree across a federation. In the U.S., states can learn from the required public filings and the presentations prompted by public notice requirements. If states had to more actively seek out information about demonstration projects from one another, it is much less likely that innovative ideas would spread from one state to another. The 1915(c) waiver models have also successfully spread from one state to many others, which has successfully supported innovative approaches to the home and community-based sector.

On the other hand, despite the ostensible, time-limited nature of most waivers, it is politically difficult for one party (federal or state government) to end one that the other party wants to continue, even when

the waiver has not successfully achieved its purposes. In addition, waiver authorities are sometimes co-opted to accomplish ideological or political objectives.

In the U.K., there has been a unique experience with an administrative delegation to local government through the GM Partnership. This experience demonstrates that the efforts to break down barriers and build relationships across providers is an important and resource-intensive first step toward integration across care sectors. Moreover, without regulatory changes or exemptions, it seems that the objective of care integration, for example across health and social care, may not be realized.

In France, the reform-oriented waivers with a specific purpose of encouraging innovation have demonstrated some success in terms of the evidence of impacts, and scalability beyond the initial pilot program. These have required significant investment, with a requirement (and funding) for evaluation. While the recent legislative change to formalize and streamline the administrative process for applying for exemptions may have the effect of encouraging pilot programs from a diverse set of stakeholders, it is too early to tell what impact it might have on care delivery or patient outcomes.

**Table 1. Selection of innovative care delivery models through waivers or administrative delegation**

Reform Approach	Primary Need	Primary Aim	Geographic Boundary, Beneficiaries, Structure	Timeframe
<b>Hospital funding reform</b> - Section 1814(b) Social Security Act	To reduce per capita hospital expenditures and test all-payer system for hospital payment (all papers pay the same fee per service), a global budget cap in 2014, and expanded all-payer model to some physician and long-term care services in 2019.	Exempt hospitals in Maryland from national payment system.	Maryland	Has been in place for 40 years; in 2018 it was extended to 2023.
<b>Shifting care from institutions to home</b> -Section 1915c Social Security Act	To receive exceptions from Medicaid rules governing institutional care.	Most waivers submitted under 1115 seek to support the needs of people in their homes rather than in institutional settings.	Section 1902(a)(1) can target waivers to a particular area of the state. Section 1902(a)(10)(c)(i)(III) allows states to provide Medicaid to people who would otherwise be eligible only if in an institutional setting.	No time limits; unless targeted to a specific population then approval period is for 5 years).
<b>Deep integration across care sectors</b> - Greater Manchester Health and Social Care Partnership	Devolution to integrate care, including health and social services.	Development of local care organizations to bridge gaps between medical and preventative approaches, along with acute care re-organization.	Greater Manchester. Requires parliamentary approval. Chief officer is an employee of the NHS and accountable to them. Local partners deliver coordinated health services.	Health and social care agreement commenced 2015.
<b>Improving care pathways for at-risk elderly</b> - PAERPA	Maximize coordination in care provision with emphasis on prevention of loss of autonomy and holistic care.	Improve quality of life of elderly people and their relatives, increase the efficiency of health and social care for elderly people by developing health care pathways.	9 areas in two waves. Elderly people (75+) at risk of loss of autonomy. Funding is at the national level.	Commenced in 2014 as a pilot program, currently ongoing. Includes a continuous evaluation process under supervision from DREES <sup>6</sup>

<sup>6</sup> La direction de la Recherche, des Études, de l'Évaluation et des Statistiques

			Regional intervention fund allocates annual payment to regional health agency responsible for pilot.	and social security department.
<b>Financial incentives for team-based care</b> - ENMR	Support coordination of care and inter-professional collaboration.	Enhance the organization of care and provide new services to patients and give financial intensive for collaborative working.	Targeting primary health care organizations. 300 organizations in 2014. Mainly serve under-privileged urban areas.	Commenced in 2009; renewed in 2014 and in 2015. In 2015, the ministry of health widened its scope to cover new multi-disciplinary settings.

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The North American Observatory on Health Systems and Policies (NAO) is a collaborative partnership of interested researchers, health organizations, and governments promoting evidence-informed health system policy decision-making. Due to the high degree of health system decentralization in the United States and Canada, the NAO is committed to focusing attention on comparing health systems and policies at the provincial and state level in federations.