

INNOVATION IN THE UNITED STATES HEALTH-CARE SYSTEM'S ORGANIZATION AND DELIVERY

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SUMMARY

The COVID-19 pandemic has had a galvanizing effect on policy-makers in the U.S. who are trying and testing innovations in delivering government-insured health care that Canada would be wise to take note of and learn from.

As in Canada, the federal government in the U.S. is limited in how directly it can influence health-care delivery, even within programs such as Medicare and Medicaid that receive federal funding. However, it has used its significant funding power to offer states incentives to promote federal priorities. As a result, dozens of states have expanded eligibility and benefits in line with federal priorities in exchange for additional funding.

The U.S. government has also encouraged states to experiment with innovative delivery or financing approaches within Medicaid by offering temporary, extendable waivers that exempt novel concepts from meeting all Medicaid requirements. This has allowed states to try new programs that target the expansion of benefits coverage. One waiver-based program, for example, allows elderly individuals to employ friends and relatives as home caregivers as an alternative to institutionalization. Digital-health initiatives have also been accelerated in the U.S. during the pandemic, including loosening restrictions to allow telehealth visits and “hospital-at-home” programs, which allow acute-care and post-acute care patients to convalesce in their own residences through remote monitoring and drug delivery.

Recent payment reforms in the U.S., meanwhile, include allowing health-care providers to voluntarily band together to share medical and financial responsibility for providing quality, co-ordinated care with lower costs, resulting in notable savings. Episode-based, bundled payments for complete courses of therapy for certain conditions have lowered some costs with equal or better quality of care. Other promising payment-reform initiatives involve managed care programs with private sector participation in care and insurance offering bundles of benefits not provided by traditional government coverage.

The health-care challenges experienced during the pandemic have also prompted the U.S. government to take a more active role in promoting more resilient supply chains for drugs and medical equipment, to reduce dependence on offshore manufacturers and introduce more transparency into the drug supply chain. It is also providing funds for training grants and student-loan repayment relief for health-care workers, to help ensure there are enough professionals being trained for the health-care workforce now and into the future.

These efforts demonstrate how health policy-makers in the U.S., in light of the COVID-19 pandemic, are driven by innovation in navigating the trade-offs between delivering quality care, expanding care, controlling costs, and allowing for regional autonomy. These considerations are not unlike those faced by Canadian policy-makers, who can learn from American innovations to help Canada emerge from the pandemic with a stronger health-care system.

INNOVATION DANS L'ORGANISATION ET LA PRESTATION DU SYSTÈME DE SANTÉ AUX ÉTATS-UNIS

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RÉSUMÉ

La pandémie de COVID-19 a eu un effet galvanisant sur les décideurs politiques aux États-Unis qui essaient et testent des innovations dans la prestation de soins de santé assurés par le gouvernement. Le Canada serait avisé d'en prendre note et d'en tirer des leçons.

Comme au Canada, le gouvernement fédéral des États-Unis est limité dans sa capacité d'influence directe sur la prestation des soins de santé, même au sein de programmes comme Medicare et Medicaid qui reçoivent un financement fédéral. Cependant, il a utilisé son important pouvoir de financement pour offrir aux États des incitations à promouvoir les priorités fédérales. En conséquence, des dizaines d'États ont élargi l'admissibilité et les avantages conformément aux priorités fédérales, en échange d'un financement supplémentaire.

Le gouvernement états-unien a également encouragé les États à expérimenter des approches innovantes de prestation ou de financement au sein de Medicaid en offrant des dérogations temporaires et extensibles qui dispensent les nouveaux concepts de répondre à toutes les exigences de Medicaid. Cela a permis aux États d'essayer de nouveaux programmes visant à étendre la couverture des prestations. Un des programmes basés sur une telle dispense permet, par exemple, aux personnes âgées d'employer des amis et des parents comme soignants à domicile comme alternative à l'institutionnalisation. Les initiatives de santé numérique ont également été accélérées aux États-Unis pendant la pandémie, notamment en assouplissant les restrictions pour autoriser les consultations de télésanté et les programmes « d'hospitalisation à domicile », qui permettent aux patients en soins de courte durée ou post-actifs de faire leur convalescence dans leur résidence grâce à la surveillance à distance et à la livraison de médicaments à domicile.

Par ailleurs, les récentes réformes de paiement aux États-Unis permettent aux fournisseurs de services de santé de s'unir volontairement pour partager la responsabilité médicale et financière dans la prestation de soins coordonnés de qualité à moindre coût, ce qui se traduit par des économies notables. Les paiements groupés pour des traitements complets dans certaines conditions ont permis de réduire certains coûts avec une qualité de soins égale ou supérieure. D'autres initiatives prometteuses

de réforme des paiements comprennent des programmes de soins gérés avec la participation du secteur privé, ou encore, des assurances qui proposent un ensemble de services non fournis par la couverture gouvernementale traditionnelle.

Les défis en matière de soins de santé rencontrés pendant la pandémie ont également incité le gouvernement des États-Unis à jouer un rôle plus actif dans la promotion de chaînes d'approvisionnement plus résilientes pour les médicaments et le matériel médical, afin d'atténuer la dépendance à l'égard des fabricants étrangers et d'introduire plus de transparence dans la chaîne d'approvisionnement des médicaments. Le gouvernement offre également des fonds pour des bourses de formation ou pour l'allègement du remboursement des prêts étudiants, afin de garantir qu'il y aura suffisamment de professionnels formés pour assurer la main-d'œuvre en santé maintenant et à l'avenir.

Ces efforts montrent comment les décideurs politiques de la santé aux États-Unis, à la lumière de la pandémie de COVID-19, sont motivés par l'innovation pour négocier les compromis entre la prestation de soins de qualité, l'expansion des soins, le contrôle des coûts et l'autonomie régionale. Ces considérations ne sont pas sans rappeler celles auxquelles sont confrontés les décideurs canadiens, qui pourraient s'inspirer des innovations états-uniennes pour aider le Canada à sortir de la pandémie avec un système de santé plus solide.

GENERAL INTRODUCTION

In 2017, the federal government took a new approach to that taken in the early 2000s to move forward on health system priorities. The government worked with the provinces and territories (PTs) to identify shared health priorities for federal investments, develop common areas of action within these priorities through an FPT framework, and then negotiated bilateral agreements with each PT. COVID-19 has highlighted the need for resilient health care systems that will continue to meet the needs of Canadians today and in the future.

It is in this context that in April 2021, the School of Public Policy convened a group of health policy experts to develop research papers on various aspects of the evolution of health care in consultation with Health Canada. These experts have a diverse range of perspectives on issues related to Canadian health systems. Health Canada was consulted on the list of topics, but the orientation of each paper, the methodology, as well as the substance of the recommendations were left entirely to the discretion of the authors.

We are proud to share the result of this process. Each paper in this series of eight was subject to the intense scrutiny, and discussed extensively following detailed roundtable presentations. Two eminent health policy experts were also asked to conduct a careful double-blind review of the papers, with a special focus on rigor, readability, and relevance. We believe these policy briefs offer a rare combination of original thinking, deep subject expertise, and technical feasibility: a perfect balance between the very practical needs of the end users of the research and the independent and innovative spirit that pervades all the work originating from the School of Public Policy.

INTRODUCTION

Over the past few decades, the U.S. has attempted to bring innovation to health-care organizations and delivery systems to improve the sustainability of financing, enhance the quality of care with lower costs, and ensure the continuity of care, without disruption in health-service and technology supply. While the U.S. and Canadian health systems differ in fundamental ways, there are opportunities for sharing successes and failures. This research paper focuses on six areas of the health-care system: fiscal federalism, expanding benefits, payment reform, virtual and digital health, supply chain reforms and the health-care workforce. These areas mirror the topics addressed by the other authors in this issue. We review current issues and trends of innovation in the U.S. health-care system's organization and delivery, and outcomes of key initiatives and areas that Canadian policy-makers should consider for the future.

I. FISCAL FEDERALISM

FEDERAL-STATE FISCAL TRANSFERS FOR HEALTH CARE IN THE U.S.

The U.S. Medicaid program, which provides insurance coverage for many low-income Americans and people with disabilities, is the largest single insurer in the U.S. (with 76 million enrollees in 2021) and represents the nation's largest federal-state fiscal transfer. Medicaid is a federal-state partnership, wherein the states provide the health-care services and the federal government provides most of the funds as matching grants. Receipt of federal funds is conditional on states providing some core benefits to special populations, but otherwise, states have flexibility in designing their programs.

A formula set by Congress called the Federal Medical Assistance Percentage (FMAP) determines the amount of state spending matched by the federal government. The FMAP is based on the average per capita income for each state compared to the national average. In 2022, the federal matching rate will range from 56.2 per cent (for high-income states) to 84.5 per cent (for low-income states) (KFF 2021). These rates reflect a 6.2-percentage-point increase authorized in response to the COVID-19 pandemic. There is no cap on federal spending for Medicaid, and in return states may not impose waiting lists or enrollment caps. Under the uncapped financing model, states have less incentive to control spending, which has contributed to the increasing growth of Medicaid expenditures as a share of U.S. GDP (MACPAC 2016).

The Children's Health Insurance Program (CHIP), which provides insurance coverage primarily for low-income children whose families are ineligible for Medicaid, is also administered by states and is funded by both states and matching federal funds, calculated according to the FMAP formula. The federal match rate for CHIP is about 15-per-cent higher for each state compared to the match rate for Medicaid. Unlike for Medicaid spending, CHIP spending is capped, which in some states has resulted in more limited benefit coverage and the implementation of waiting lists or enrollment caps to control spending (Rudowitz, Artiga, and Arguello 2014). Proposals to similarly cap Medicaid spending through either block grants or per capita allotments have been common since Medicaid's inception. Such reforms, however, might limit states' abilities

to respond to changing demographics and program needs (Rudowitz 2017) or result in higher rates of uninsurance (CBO 2017).

Because the FMAP is based on income per capita, it has been criticized for failing to: 1) count state resources that are not reflected in resident income, such as revenue from energy production and other exportable products; 2) capture differences in the relative size of low-income populations between states with similar incomes per capita; and 3) incorporate information about the relative size of higher-cost populations between states, such as the elderly and disabled. The FMAP thus obscures important differences between states in terms of 1) fiscal capacity, 2) beneficiary need and 3) cost of service delivery (Peters 2008). Additionally, because the FMAP calculation is based on an average of the previous three years of income data, federal transfers sometimes fail to reflect the current economic reality of states (Peters 2008). One commonly proposed reform is to include a trigger that would automatically recalculate the FMAP for states undergoing an economic crisis (O'Mahen and Petersen 2021).

FEDERAL TRANSFERS PROVIDE INCENTIVES FOR STATES TO EXPAND ELIGIBILITY AND BENEFITS

The federal government also uses enhanced matching rates to incentivize state provision of health-care benefits beyond mandatory coverage requirements. For example, family-planning services is a mandatory coverage category under Medicaid, but states have flexibility in determining which particular services to cover. To promote broad coverage under this benefit, the federal match rate for family-planning services has been 90 per cent for all states since 1972. Other enhanced FMAP rates address care for children with medically complex conditions, clinical preventive services and adult immunizations, smoking cessation services for pregnant women and “health home” co-ordinated and holistic care for individuals with chronic conditions (Mitchell 2020).

The Patient Protection and Affordable Care Act (ACA), enacted in 2010, sought to expand Medicaid coverage to all Americans with incomes below 138 per cent of the federal poverty line by covering 100 per cent of additional state spending for these individuals (this support would gradually fall to 90 per cent after two years). Initially, eligibility expansion was perceived to be mandatory, but following a 2012 Supreme Court decision, the decision to expand eligibility and accept enhanced federal funding was left to individual states. Currently, 38 states and Washington D.C. have chosen to expand Medicaid eligibility in line with the ACA. These states have not seen an increase in state expenditures or crowding-out of other state spending (such as spending on education or transportation) and it is estimated that the states electing not to expand eligibility have effectively passed up approximately US\$43 billion in aggregate federal Medicaid funding (Gruber and Sommers 2020).

The ACA also included an additional six-per-cent federal match rate for Medicaid through its Community First Choice program for states that expand benefits coverage to include home- and community-based services for beneficiaries requiring institutional care. As of 2020, eight states have expanded care under this program (Burgdorf et al. 2020). States report several reasons for choosing not to expand care under this program, including unpredictable growth in enrollment and associated costs, shortages

in relevant staff and infrastructure, and a preference for the greater flexibility afforded by the Medicaid waivers program as an avenue for expanding these services (Burgdorf et al. 2020; Burwell 2015).

The ACA also further enhanced the CHIP match rate to incentivize states to expand CHIP eligibility to more children, raising the average federal match rate for state CHIP spending to 93 per cent. As a result of the many efforts to expand insurance coverage for children, the uninsured rate among children has steadily decreased to approximately five per cent since CHIP's establishment in 1997 (KFF 2019), even while uninsured rates among nonelderly adults have remained relatively unchanged (Rudowitz, Artiga, and Arguello 2014).

In summary, the Medicaid and CHIP programs allow for state autonomy within broadly defined requirements. Federal fiscal transfers to support these state programs are broadly intended to align with differences in need, but the basis for these allocations could be improved to better promote equity between the states. The decision whether to cap fiscal transfers to states involves a trade-off between controlling overall spending and ensuring broad eligibility and coverage. Conditional federal fiscal transfers (notably those associated with the ACA) incentivize states to address gaps in eligibility and benefits coverage in these programs, eschewing a strict top-down approach to improve equity in access. Still, differences in political ideology across states, and a desire for greater flexibility in expanding eligibility and benefits, limit the success of some of these federal efforts.

II. BENEFIT EXPANSION

The U.S. is considering expanding benefits coverage in Medicare to include hearing care, a service for which there is both a substantial unmet need and high cost burdens, especially among those with the lowest incomes (Willink, Schoen and Davis 2018). U.S. lawmakers are developing legislation that proposes to use savings from pharmaceutical pricing reforms to fund the additional costs of covering these benefits in standard Medicare (Cohrs 2021). Others propose a voluntary, premium-financed supplemental Medicare benefit to cover vision, dental and hearing care, with subsidies for low-income enrollees (Willink, Schoen and Davis 2018).

Traditionally, Medicare Advantage (MA) plans, which are the capitated payments alternative to traditional fee-for-service Medicare, and cover 26 million Americans, have been limited to providing “primarily health-related” benefits such as vision, dental and hearing care. The ability of MA to provide additional benefits was expanded in 2019 to include transportation, meal delivery, in-home support services and support for caregivers of enrollees, among other supports. Beginning in 2020, MA plans began offering Special Supplemental Benefits for the Chronically Ill, such as indoor-air-quality services, service-dog support and structural home modifications. Initial analyses show mixed results across each of these expanded benefits in terms of MA plan uptake and beneficiary enrollment, and it is too soon to know whether these initiatives will improve beneficiary outcomes, especially for those with chronic illnesses, or produce cost savings (Kornfield et al. 2021; Meyers et al. 2020).

Section 1115 Medicaid demonstration waivers permit states to apply for waivers that will allow them to test novel delivery or financing approaches beyond what is already available and without being subject to Medicaid statutory requirements such as “state-wideness” (i.e., coverage cannot be limited on the basis of where enrollees live or work) or “comparability” (i.e., the same benefits must be provided to all enrollees). These waivers are granted for a period of five years and can be extended.

The Centers for Medicare and Medicaid Services (CMS), the federal agency that administers Medicare and works with states to administer Medicaid, typically requires waivers to be budget-neutral from the perspective of the federal government (Hinton, Musumeci et al. 2019). An example of a Section 1115 waiver to expand Medicaid benefits is North Carolina’s Health Opportunity Pilots waiver, approved in 2018. This waiver permits North Carolina’s Medicaid program to cover “evidence- based non-medical services that address specific social needs linked to health/health outcomes” (Hinton, Artiga et al. 2019). Other pending and accepted waiver programs target the expansion of benefits coverage for postpartum care, substance-use disorder and mental health services for people in institutions for mental disease (Guth et al. 2020). Waiver programs other than Section 1115 specifically target the expansion of home- and community-based services (more than 300 programs nationwide) (CMS n.d. a). For example, Oregon Medicaid offers several waiver-based programs that allow elderly individuals to employ others, including friends and relatives, as home caregivers, as an alternative to institutionalization (Paying For Senior Care 2020).

The efforts to expand benefits in the U.S. demonstrate how policy-makers must consider trade-offs between controlling costs, equitably expanding benefits, and allowing for regional autonomy. Supplementing Medicare is the most direct way to expand benefits nationally for a vulnerable group (the elderly), but does not address other vulnerable groups, such as younger low-income populations and children. Medicare expansion also faces significant political obstacles given its already substantial costs to the federal government. Expanding benefits through MA plans could exacerbate inequities in access, since MA plans are not required to expand benefits even if their scope is expanded; moreover, MA plan coverage and penetration varies widely by state (Freed, Fuglesten Biniek et al. 2021). The Medicaid waivers program grants states flexibility to expand benefits for low-income populations in line with local priorities, but results in disparate coverage across the states. The budget-neutrality provision for Section 1115 waivers, while helping to rein in federal expenditures, may limit more widespread and effective use of this approach for benefits expansion; easing this regulation by conditioning additional state funding on meeting specified waiver program goals is one way forward (Albanese 2019). Finally, expanding benefits in Medicaid may not always translate to expanded access for all beneficiaries, since low payment rates limit physician participation in Medicaid (Neprash et al. 2018; Zuckerman, Skopec and Aarons 2021).

III. PAYMENT REFORMS

The U.S. government's payment policy is currently focused on improving care quality, lowering costs and rewarding value (Navathe, Emmanuel, Glied et al. 2020). The enactment of the ACA and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) has accelerated the transition from the fee-for-service model to value-based models with patient-centred incentive structures. The ACA created the Center for Medicare and Medicaid Innovation (CMMI), with a US\$19 billion budget over 10 years. (Anderson, Davis and Guterman 2015). The CMMI's initiatives span various segments of health-care delivery, including the Medicare Shared Savings Program for Accountable Care, episode-based bundled payment and primary-care transformation. While the CMMI's initiatives primarily focus on traditional fee-for-service Medicare, Medicare Advantage is rapidly expanding and accelerating Medicare's transition to a value-based insurance system. In this section, we review three major alternative payment models and Medicare Advantage, outcomes of the initiatives, and opportunities for future payment reforms. The challenge is that many of these initiatives were unable to generate substantial net savings, perhaps because participation in the programs is voluntary (Smith 2021).

PAYMENT REFORMS FOR TRADITIONAL FEE-FOR-SERVICE MEDICARE

Medicare Shared Savings Program

The Medicare Shared Savings Program is a value-based payment model in traditional fee-for-service Medicare for accountable care organizations (ACOs) to incentivize efficient care by reducing the number of hospitalizations. In this model, health-care providers voluntarily band together to form an ACO and share medical and financial responsibility for providing high-quality, co-ordinated care to patients at a cost below that of a pre-established benchmark. In 2019, ACOs in the Medicare Shared Savings Program generated US\$1.2 billion total net savings for Medicare while still meeting a baseline quality-performance standard (Verma 2020). As of 2019, nearly 30 per cent of fee-for-service Medicare beneficiaries were served by health-care providers in ACOs (Verma 2020).

Episode-based payment initiatives

CMMI has developed and tested various episode-based payment models. Among these, Bundled Payments for Care Improvement (BPCI) is a voluntary episode payment model which provides a single, comprehensive payment amount for all services provided during a patient's episode of care within a specific time frame and across the continuum of care (CMMI n.d. a). The evidence suggests that BPCI lowered episode-based costs with equal or better quality of care for surgical procedures (Glickman, Dinh and Navathe 2018) but did not result in substantial net savings, given the contractual costs to attract participants in voluntary models (Smith 2021).

Primary-care transformation initiatives

Comprehensive Primary Care (CPC) is the largest primary-care transformation initiative that CMMI has developed. It is a public-private partnership model to provide co-ordinated, planned and continued primary care. Since 2012, CMMI has tested whether population-based care management fees and shared savings opportunities to participating primary-care providers can achieve the goals of the initiative. Based on the lessons learned from CPC in seven selected regions, CMMI launched Comprehensive Primary Care Plus (CPC+), a five-year advanced primary-care medical home model in 14 regions in 2017 (AHRQ n.d.; CMMI n.d. b). The CPC+ payment model includes non-visit-based Care Management Fee (CMF) and performance-based incentive payments, in addition to payment under the Medicare physician fee schedule. In 2021, 2,610 primary-care practices are participating in CPC+ supported by 52 aligned payers in 18 regions.

MEDICARE ADVANTAGE EXPANSION

MA is an alternative to traditional fee-for-service Medicare (which covers hospital and physician services and prescription drugs) and provides “all-in-one” bundled benefit packages to Medicare beneficiaries through private insurance companies (CMS n.d. b). Among many payment reforms and initiatives, MA is the fastest-growing model and business segment for many health plans, with approximately eight-per-cent growth per year in recent years (Freed, Damico and Neuman 2021). The driving force of this transition is that MA plans provide supplemental benefits outside traditional Medicare coverage, such as eyeglasses, transportation, dental care, fitness memberships and various telehealth benefits. Despite the extra benefits to enhance consumers’ experience and health, about 60 per cent of enrollees pay no premium for their MA plan, which is a strong incentive for Medicare beneficiaries to join the program.

MA plans receive the fixed per-member, per-month fee for each Medicare beneficiary enrolled in the plan, regardless of the beneficiary’s service utilization. Revenue for MA plans is directly impacted by Stars, the CMS’s quality ratings that reflect plan performance on more than 40 quality measures, including customer-experience metrics. Since CMS posts quality ratings of MA plans to provide information about plans to beneficiaries, star ratings impact a plan’s growth and retention as well.

NEXT STEPS FOR PAYMENT REFORM

The evidence suggests that participation in these alternative payment models (APMs) is lower in areas with vulnerable populations, and these programs have the potential to exacerbate health-care disparities (Yasaitis, Pajerowski, Polsky and Werner 2016). Developing measures to monitor health disparities and including them among APM performance metrics may address the issue without major structural changes to the current framework. All three APMs are voluntary participation-based models, which may limit their impact. Creating a path to mandatory participation would be an important next step to accelerate Medicare’s movement toward value-based payment.

Regarding Medicare Advantage, penetration of these plans varies widely across states, ranging from one per cent in Alaska to 49 per cent in Florida (Freed, Fuglesten Biniek, et al. 2021). This is partly due to variance in the number of insurers offering MA plans in different areas and the ability of the health plans to create a network of providers in more remote areas. Also, per-enrollee cost and its growth rate in MA exceeds the per-beneficiary cost and its growth rate in traditional fee-for-service Medicare (MedPAC 2020). Finally, it is unknown whether MA offers better quality of care compared to traditional fee-for-service Medicare, and further research is needed. CMS recently announced a new methodology for the MA plan quality-rating system, which will increase the weight of patient experience metrics to 57 per cent by 2023 (Carlton et al. 2020).

IV. DIGITAL HEALTH REFORMS THAT EXPAND THE OPPORTUNITIES FOR CARE DELIVERY

The U.S. has accelerated the use of digital and virtual care amid the COVID-19 pandemic. The quick adoption of telehealth was necessary given increased patient reluctance for in-person visits and patient safety concerns. The recent rapid transition was facilitated by the government's actions to waive restrictions on coverage of telehealth services. While telehealth visits have garnered most of the public's attention, the shift to virtual care in the U.S. is expanding to various health-care segments beyond office visits or primary-care services.

TELEHEALTH VISITS

In 2020, nearly 80 per cent of physician visits in the U.S. were replaced with telehealth visits (AHA 2019). Although the rapid adoption was driven by the unprecedented public health emergency, an increasing number of surveys and research suggest that the virtual-care model will continue after the pandemic. For example, 74 per cent of users of telehealth visits reported high satisfaction (Bestsenny et al. 2021). However, despite the large increase in the use of telehealth nationwide, great variation in its adoption exists across regions. Health centres in rural areas experienced greater challenges in providing telehealth services because of the lack of providers and the cost of implementing the new technology (CDC 2021).

The use of telehealth is more common in several specialties. According to a pre-pandemic study, the most likely specialists to use telehealth to interact with patients were radiologists (with 40 per cent being likely to do so) and psychiatrists (28 per cent), while gastroenterologists (eight per cent) and immunologists (six per cent) were least likely (Kane and Gillis 2018). This changed during the pandemic, with nearly 70 per cent of endocrinologists and 57 per cent of gastroenterologists reporting that they use telehealth frequently, suggesting dramatic shifts in the distribution and frequency of telehealth use (Patel, Mehrotra, Huskamp et al. 2021).

The Medicare program has two different rates that pay for clinical services: a rate paid in the clinician's office and a rate that is paid when the same service is received at the hospital. The clinician's payment rate is higher in the office than in a hospital facility, but

the total amount is lower in the clinicians' office since no facility fee is paid. Before the pandemic, Medicare had limited coverage for many telehealth services and its payment rate for a telehealth visit was based on the lower amount paid to clinicians in the facility (e.g., hospital outpatient centres) (Koma, Cubanski and Neuman 2021). In response to the public health emergency, CMS expanded coverage for various services available for telehealth, temporarily approving nearly 100 new services, in addition to relaxing certain restrictions on its use. Under the telehealth parity policy, Medicare pays for telehealth services, including audio-only services, as if they were provided in person. This means that telehealth services administered by non-facility-based clinicians receive a higher net payment than those administered by facility-based providers (Koma, Cubanski and Neuman 2021). This policy may change as the public-health emergency fades out. There is also increased monitoring of fraud, since telehealth visits are more susceptible to misreporting.

HOSPITAL-AT-HOME

Hospital-at-home is an example of an innovative model that provides hospital-level care in a patient's home for health conditions requiring hospitalizations, including acute conditions. The hospital-at-home model has evolved with a wide array of virtual- and digital-health innovations that enable remote monitoring and diagnostic tests, and a drug administration and delivery system, as well as 24/7 virtual visits via telehealth. There is evidence that hospital-at-home can reduce spending compared with traditional hospital care, while achieving equal or better health outcomes for a selected set of health conditions suitable for at-home care (Cryer, Shannon, Van Amsterdam and Leff 2012), particularly for patients with well-defined treatment protocol (e.g., chronic obstructive pulmonary disease) or those who are vulnerable to hospital-acquired conditions (Leff, Burton, Mader et al. 2005).

In 2020, CMS launched the Hospitals Without Walls program to provide regulatory flexibilities to treat eligible patients in their homes for post-acute care, and the Acute Hospital Care at Home program, which expands the application of the model to acute conditions (CMS 2020). The number of approved health systems participating in the Acute Hospital Care at Home program rapidly increased from six in November 2020 to 53 systems for 116 hospitals in April 2021. In response to the changes in payment policy, large providers and startup companies, including Amazon Care, are joining forces to expand the coverage of home-based health care (AHA 2021).

DIGITAL HEALTH-CARE DEVICES AND APPLICATIONS

The U.S. Food and Drug Administration's definition of digital health includes mobile health, health information technology, wearable devices, medical applications, and artificial intelligence that enhance health-care delivery for the individual. The Food and Drug Administration (FDA) recently created the Digital Health Center of Excellence to provide guidance for digital-health stakeholders, such as developers, and to develop regulatory frameworks for product review and approval with FDA standards (FDA 2020). Since these technologies actively use and exchange personal health information among many devices, software programs and health systems, the

increasing interoperability prompted cybersecurity concerns, and it has become one of the priority areas of the regulatory review.

Although commercial insurance payers have started paying for digital therapeutics by introducing a digital formulary, there have been various challenges for CMS to pay for digital-health devices and applications. These challenges include misalignment between the coding system and therapeutic benefits of digital health, and Medicare's benefit structure based on traditional care sites and delivery protocols (Ostrovsky 2020).

NEXT STEPS FOR DIGITAL HEALTH

While there is increasing consensus on the need to continue expanding coverage of telehealth services after the pandemic ends, much research into developing cost, quality and monitoring measures will be needed. For example, there have been several fraud cases involving telehealth services and related supplies that were never used for patients (DoJ 2020; Koma, Cubanski and Neuman 2021). Establishing guidelines for appropriate use of telehealth and digital health-care devices to improve patient access to health-care services and ensure quality of care is a critical next step. Moreover, the rise of telehealth and digital health care have raised a concern regarding health disparities, given the lack of necessary technology and support to access the service among communities with high poverty rates and in rural areas with limited IT infrastructure (Patel, Mehrotra, Huskamp et al. 2021). Addressing these challenges and understanding the needs of the most vulnerable is an important mission to achieve the goals of these transitions.

V. SUPPLY CHAIN REFORMS THAT GUARANTEE ACCESS TO CRITICAL INPUTS

Shortages of health-care inputs, especially pharmaceuticals, have historically been a source of frequent challenges to U.S. hospitals, pharmacies, and patients (Ventola 2011). The COVID-19 pandemic expanded and exacerbated such shortages, exposing serious vulnerabilities in the U.S. pharmaceutical supply chain and revealing a visible threat to U.S. public health (Socal, Sharfstein and Greene 2021). Shortages of prescription drugs, personal protective equipment (PPE) and vaccines highlighted the need to have a redundant supply and to not have the U.S. dependent on a single source for these and other essential health-care inputs. The globalized nature of the U.S. supply chain became recognized as a source of vulnerability, especially in times of crisis (Socal, Sharfstein and Greene 2020).

KEY FACTS

Before the COVID-19 pandemic, more than 100 drugs were in shortage according to the U.S. Food and Drug Administration (FDA) (FDA 2021). The pandemic expanded these shortages to over 150 drugs (ASHP 2020). According to the FDA, most drug shortages involve low-cost injectable drugs that have a generic equivalent and have been on the U.S. market for a long period of time (a median of 35 years) (FDA 2019).

The U.S. relies strongly on a globalized supply chain for pharmaceuticals and other health-care inputs. The FDA estimates that, among finished drug products consumed in the U.S., 37 per cent are domestically produced, followed by those produced in India (24 per cent) and the European Union (18 per cent). Active pharmaceutical ingredients (APIs) used in the U.S. mostly come from India (31 per cent) and the European Union (31 per cent), followed by China (14 per cent) and the U.S. (12 per cent) (FDA 2019). However, the FDA does not fully track the supply chain for each given drug, and retailers have access to multiple sources (U.S.- China Economic and Security Review Commission 2019). It is estimated, for example, that up to 70 per cent of APIs nominally made in India are actually sourced from China (White House 2021). For PPE, the dependency in the global supply chain is even higher and more concentrated in China. About 90 per cent of all N95 masks used in the U.S. are imported, mostly from China, and China is the only country that produces nonwoven fibres, the raw material needed to manufacture these masks (Dai, Bai and Anderson 2020).

The FDA has identified three root causes of U.S. drug shortages (FDA 2019): 1) lack of incentives for manufacturers to produce less-profitable drugs, 2) lack of methods for rewarding manufacturers for robust quality-management systems and 3) logistical and regulatory challenges that make it difficult for the market to recover from a disruption.

Most non-crisis shortages are typically triggered by manufacturing problems, including weather and other events that disrupt production. Crisis-related shortages are driven mostly by sharp increases in demand, exceeding manufacturers' production capacity.

The COVID-19 pandemic exposed additional vulnerabilities that stem from the increased reliance on a global supply chain. Lockdowns, understaffing and travel and export bans have jeopardized production and distribution of medicines and equipment across the world. At the same time, travel restrictions have limited the FDA's capacity to inspect manufacturing plants overseas, reducing its ability to authorize new sources of drugs and supplies (Socal, Sharfstein and Greene 2021).

RELEVANT POLICY INITIATIVES

The Biden administration has developed policies to address supply chain vulnerabilities and increase the supply chain's resilience to future crises. In June 2021, the Biden administration issued an executive order establishing a series of supply chain policies (White House 2021).

The executive order recognizes a need to develop novel platform technologies to increase domestic manufacturing capacity of key pharmaceuticals and ingredients, such as APIs and finished dosage forms (including supportive-care fluids). The executive order establishes a public-private consortium to develop advanced manufacturing capabilities for the domestic production of essential medicines. The consortium's first task is to select 50 to 100 drugs to be the focus of this effort. The FDA's essential-medicines list will likely serve as a basis for the identification of these drugs (FDA 2020). The executive order leverages the buying power of the nearly US\$600 billion in federal contracting to strengthen domestic supply chains for critical products. This includes developing new processes for identifying critical products

to be prioritized for federal purchase under the Buy American Act. The U.S will use diplomatic tools to expand multilateral engagement on supply chain vulnerabilities, particularly through groupings of like-minded allies, to encourage and facilitate resilient supply chains.

Transparency in the supply chain is a priority. This involves the FDA developing and requiring quality metrics that accurately reflect manufacturing practices and the quality of drugs produced by different manufacturers. In addition, measures are being developed to increase traceability and monitoring of manufacturers and supplies. Currently, there are no databases that identify approved API sources for potential generic drug manufacturers. An FDA database would accelerate the process of finding alternative suppliers that meet agency requirements whenever a shortage potential is detected (Socal, Sharfstein and Greene 2021). There have also been calls for stockpiling and stress-testing the supply chain, especially for PPE and other non-drug products (Dai, Bai and Anderson 2020), strategies whose potential remains to be understood. The suggested reforms for manufacturing and supply chain distribution by national coordination may lower the costs of some drugs; this is an area worth further examination.

VI. HEALTH WORKFORCE

The U.S. federal government has long recognized the need for ensuring there is an appropriate number of health professionals working in the labour force. Estimates predict that, by 2033, the U.S. could have 54,100 to 139,000 fewer physicians than will be needed to meet the demand for primary and specialized care (Association of American Medical Colleges 2020). The main drivers of this impending shortage of health professionals are: the aging of the U.S. population (creating increased need); the retirement of older physicians (reducing supply); and the inequitable geographic distribution of health professionals (creating barriers to care for underserved populations) (Association of American Medical Colleges 2020).

KEY FACTS

At 2.6 doctors per 1,000 inhabitants, the U.S. has one of the lowest levels of physician supply among industrialized countries (OECD 2021). About a quarter of U.S. physicians are international medical graduates (Ranasinghe 2015).

FINDING THE RIGHT BALANCE IN THE NUMBER OF HEALTH PROFESSIONALS

The Department of Health and Human Services funds a series of training programs to expand and enhance the health workforce in the U.S. It funds seven research centres nationwide, based in academic centres focusing on different aspects of the workforce (e.g., behavioural health, geriatrics, public health, oral health, children's health, nursing, and diversity). The U.S. government recognizes that the mobility of health professionals is a significant issue, and clinicians trained in one state will often practice in another state, so conducting the analysis at the national level is important.

Increasing the number of primary-care providers is a main policy goal. The federal

government offers grants to schools, hospitals and health departments that offer training programs, faculty development and health-care services. The federal government also offers cost-sharing grants to enable states and territories to operate their own loan-repayment programs for clinicians in medical, mental and behavioural, and dental health-care fields. Other training grants, such as Title VII of the Public Health Service Act, support primary-care clinician training, as well as curriculum and faculty development, and programs such as the National Health Service Corps help bring a greater number of primary-care physicians to underserved areas (Bodenheimer and Pham 2010). The ACA reauthorized and expanded these programs. However, such programs have been historically underfunded and have had limited success, partially because they do not address other factors, such as the perceived low prestige of primary care, the significant financial burden of medical-school loan debt, and the prospect of higher earnings in other specialties. After the ACA, the difference in salary between specialists and primary-care physicians decreased (Hsiang et al. 2020), but the number of primary-care physicians has continued to grow more slowly than the number of specialist physicians (Barbey et al. 2017).

CLOSING NOTE

In conclusion, fiscal federalism has been the primary means for incentivizing states to expand eligibility and benefits under public insurance programs. There has been a recent push to expand benefits for the elderly through traditional Medicare and Medicare Advantage plans. The U.S. has tested and implemented various innovative payment models to transform a fee-for-service system to a value-based system. In response to the COVID-19 public health emergency, the U.S. accelerated the use of digital and virtual care, and the transition was supported by the government's swift action to improve access and affordability of the new care model. Further research on cost, quality, and monitoring measures is needed to integrate digital health into mainstream health care. Efforts to increase the resilience of the U.S. supply chain for pharmaceuticals and other health care inputs are an important part of a larger effort to set up a supply chain management system that can operate not only during times of crisis, but also in more normal times that follow. Similarly, strategies to increase the health workforce, ensure diversity, expand the number of primary-care physicians, and improve the distribution of health-care professionals to underserved areas are key to maintaining adequate levels of the health workforce to meet the needs of the U.S. population now and into the future.

Table 1 Summary and assessment of innovations in the U.S. health-care system’s organization and delivery

Area of innovation	Key efforts and proposals	Assessment
<p><i>Fiscal federalism</i></p>	<ul style="list-style-type: none"> - Transfers to key state health programs are based on state average income per capita: <ol style="list-style-type: none"> 1. Medicaid: States receive uncapped federal funding to administer program within broad requirements. 2. CHIP: States receive capped federal funding to cover some low-income children who are ineligible for Medicaid. 	<ul style="list-style-type: none"> - Federal fiscal transfers broadly align with state differences in financial need; potential improvements to better reflect need include accounting for: <ol style="list-style-type: none"> 1. State resources not measured simply by resident income. 2. Differences in relative size of low-income populations in states with similar average incomes per capita. 3. Differences in relative size of high-cost populations, such as the elderly or disabled. 4. Short-term changes or crises in state fiscal capacity. - The decision whether to cap federal transfers involves a trade-off between controlling overall spending or ensuring broad eligibility and coverage across the nation.
	<ul style="list-style-type: none"> - Additional federal-state transfers incentivize expansions of eligibility and benefits: <ol style="list-style-type: none"> 1. E.g., Family planning: Federal government matches 90 per cent of state spending. 2. Affordable Care Act (2010): Federal government covers 100 per cent of state spending for expanding Medicaid coverage to individuals with incomes below 138 per cent of federal poverty level (gradual decrease to 90 per cent); additional funding for states to cover home- and community-based services; additional funding to expand CHIP coverage. 	<ul style="list-style-type: none"> - Medicaid and CHIP allow substantial state autonomy within broad core requirements. - Conditional federal transfers incentivize voluntary state expansion of eligibility and benefits to improve equity in access. - Differences in political ideology across states and a desire for greater flexibility in expanding eligibility and benefits limit the success of some of these federal efforts.
<p><i>Expanding benefits</i></p>	<ul style="list-style-type: none"> - Comprehensive vision-, dental- and hearing-care coverage in Medicare: <ol style="list-style-type: none"> 1. Expand Medicare core benefits, financed by savings from pharmaceutical pricing reform (under legislative consideration). 2. Create voluntary supplemental Medicare benefit, financed by premiums with income-based subsidies (proposed). 	<ul style="list-style-type: none"> - Comprehensive vision-, dental-, and hearing-care is a high priority given substantial unmet need and high cost burdens, especially among those with the lowest incomes. - National reach for a vulnerable population (those aged over 65). - Controlling costs and setting the appropriate rates are significant concerns.
	<ul style="list-style-type: none"> - Medicare Advantage expansion: <ol style="list-style-type: none"> 1. Expansion of “primarily health-related” benefits to include nonmedical services (2019). 2. Coverage of Special Supplementary Benefits for the Chronically Ill (2020). 	<ul style="list-style-type: none"> - May have less impact on federal spending than Medicare expansion. - May exacerbate inequities in access due to substantial variation in plan coverage and penetration.
	<ul style="list-style-type: none"> - State Medicaid waivers to expand social service benefits: <ol style="list-style-type: none"> 1. E.g., North Carolina’s Health Opportunity Pilots to address social determinants of health (2018). 	<ul style="list-style-type: none"> - Recognizing the trade-off between medical and social service benefits. - Alternative means for expanding benefits among low-income populations. - Use varies widely across states. - Loosening budget-neutrality provision could increase use by states.

<p><i>Payment reforms</i></p>	<ul style="list-style-type: none"> - Under the ACA of 2010 and the MACRA of 2015, the U.S. has made efforts to accelerate the transition from fee-for-service to value-based models: <ol style="list-style-type: none"> 1. Medicare Shared Savings Program: Accountable care organizations (ACOs) provide incentives to reduce inpatient hospital care by allowing hospitals to share in savings from less inpatient use. 2. Bundled Payment for Care Improvement (BPCI): Episode-based payment model for all services, including hospital physician drug and rehabilitation services. 3. Comprehensive Primary Care initiatives: Public-private partnership to provide co-ordinated care by paying directly for care co-ordination. 4. Medicare Advantage expansion: "All-in-one" bundled benefit package alternative to fee-for-service Medicare. 	<ul style="list-style-type: none"> - In 2019, ACOs in the Medicare Shared Savings Program generated US\$1.2 billion net savings to Medicare while meeting the quality performance standard. - BPCI achieved lower costs with equal or better quality of care for surgical procedures, but not for chronic conditions. - All of the three APMs are voluntary participation-based models, which may limit the impact of the payment model to a smaller scale. - Per-enrollee cost and its growth rate in Medicare Advantage exceeds the per-beneficiary cost and its growth rate in traditional fee-for-service Medicare.
<p><i>Digital health</i></p>	<ul style="list-style-type: none"> - The United States has accelerated the use of digital and virtual care amid the COVID-19 pandemic, and the shift is expanding to various health-care segments. <ol style="list-style-type: none"> 1. Telehealth visits: In response to the public health emergency, Centers for Medicare and Medicaid Services (CMS) expanded coverage for various services available for telehealth. Eighty per cent of physician visits were replaced with telehealth visits. 2. Hospital-at-home: In 2020, CMS launched the Hospitals Without Walls program to provide regulatory flexibility to treat eligible patients in their homes for acute and post-acute care. 3. Digital health-care devices and apps: The FDA recently created the Digital Health Center of Excellence to provide guidance for digital-health stakeholders. 4. Medicare covers the use of medical devices approved under the FDA's breakthrough designation for four years. 	<ul style="list-style-type: none"> - Seventy-four per cent of the telehealth-visit users reported high satisfaction. Research on developing the cost, quality and monitoring measures will be needed to expand coverage of telehealth services after the pandemic ends. - Wide adoption of the model beyond the pandemic requires a large number of patients with high-cost health conditions to generate impactful savings and achieve economies of scale. - The coverage determination of digital health-care devices does not account for therapeutic value and quality. Establishing systematic ways to measure value in a quantifiable manner, and incorporating them into payment and coverage decisions, would be critical to incentivize the development of significantly innovative technology. - It will be challenging to monitor appropriate use in telehealth.
<p><i>Supply chain</i></p>	<ul style="list-style-type: none"> - In June 2021, the Biden administration issued an executive order establishing a series of policies to strengthen the resilience of the U.S. supply chain, focusing on pharmaceuticals. These policies include: <ol style="list-style-type: none"> 1. Supporting the development of novel technologies to increase domestic manufacturing capacity for key pharmaceuticals and ingredients. 2. Establishing a public-private consortium to develop advanced manufacturing capabilities for the domestic production of essential medicines. The consortium's first task will be to select 50 to 100 drugs to be the focus of this effort. 3. Leveraging the buying power of the nearly US\$600 billion in federal contracting, to strengthen domestic supply chains 4. Using diplomatic tools to expand multilateral engagement on supply chain vulnerabilities. 	<ul style="list-style-type: none"> - It is too early to evaluate the effect of the Biden administration's supply chain policies. However, some gaps in these policies can already be identified. These indicate what the next steps in U.S. pharmaceutical supply chain policies should be: <ol style="list-style-type: none"> 1. Expanding the FDA's drug-shortage surveillance system to better track shortages at local levels. 2. Increasing the transparency in the supply chain and improving traceability and monitoring of manufacturers and supplies. 3. Developing and requiring quality metrics that accurately reflect manufacturing practices and the quality of drugs produced by different manufacturers. 4. In addition, there have been calls for stockpiling and stress-testing the supply chain, especially for PPE and other non-drug products.

<p><i>Health workforce</i></p>	<ul style="list-style-type: none"> - <i>Research:</i> The Health Services and Resources Administration (HRSA) funds seven nationwide workforce research centres focusing on behavioural health, geriatrics, public health, oral health, children’s health, nursing, and diversity. - <i>Grants:</i> HRSA and Title VII of the Public Health Service Act support direct training programs; HRSA also supports states’ loan-repayment programs for clinicians in priority fields. - <i>Recruitment:</i> National Health Service Corps pays primary-care physicians to work in underserved areas. - <i>Payment:</i> The Affordable Care Act (ACA) authorized temporary fee increases for primary-care physicians and supported accountable care organizations, which tend to employ primary-care providers. 	<ul style="list-style-type: none"> - Loan-repayment programs, training grants, and service programs have been historically underfunded and have had limited success. - After the ACA, the difference in salary between specialists and primary-care physicians was reduced, but the number of primary-care physicians continued to grow at a fraction of the growth in the number of specialist physicians. - Disparities across states in availability of medical professionals exist.
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