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Ten Year Sunset Rule for Healthcare Regulation Is a Nonstarter and Discouragement to Post-COVID-19 Investment

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Abstract

U.S. healthcare delivery has not benefitted from the same productivity growth as many other service industries, such as bricks and mortar retailing, a loss that has gravely diminished cost control and access. Regulatory capture, which creates barriers to venture capital (VC) investment, has curtailed VC investment in the new entrants that can increase productivity. The important delivery innovations that occurred during the COVID-19 pandemic demonstrate what can happen with concurrent review of regulations. The new Health and Human Services' ten-year period for review of regulations, which is longer than the VCs' 5-6-year investment cycle, will deter their investment by permitting potentially obstructive regulations to remain in place.

Ten Year Sunset Rule for Healthcare Regulation Is a Nonstarter and Discouragement to POST-COVID-19 Venture Capital Investment

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U.S. **h**ealthcare delivery has not benefitted from the same productivity growth as many other service industries, such as bricks and mortar retailing, a loss that has gravely diminished cost control and access. As every U.S. President for the past four decades has recognized, archaic regulations likely stood in the way; but a new U.S. Department of Health and Human Services (HHS) rule for a ten-year retrospective review of regulations that affect small entities will not solve the problem.[1]

Some claim that productivity growth is virtually impossible in healthcare; but other labor-intensive businesses have achieved it. Innovation was an important component of productivity growth. For example, some bricks and mortar retailer productivity growth originated with newly established firms such as the discounting TJX companies, incorporated in 1987, which grew to 4,000 stores in 2017. But, while labor productivity in TJX's retail category increased by 5.5% between 2018-2019, annual healthcare labor productivity grew by only 4% from 1993- 2017 and was essentially flat for the past decade.[2]

One likely reason for the lack of productivity growth is that powerful *status quo* healthcare delivery and insurance firms have used regulatory capture to curtail the productivity that can be created by new entrants.[3] The innovations that flourished during the COViD-19 period – for example, telemedicine and retail healthcare –demonstrate the potential of health care delivery productivity growth when VC investment–throttling regulations were lifted

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The HHS rule to remedy regulatory capture requires that any of its regulations will expire ten years after issue, absent a review to determine whether it has a substantial economic impact on a number of small entities. The rule's proposal occasioned legitimate objections from HHS's powerful *status quo* stakeholders, ranging from the American Hospital Association, Medicaid, CHIP, and MPAC.[4,5] But no comments went to the heart of the matter: the retrospective review rule is unlikely to help the very small entities on which it is focused because its ten-year expiration date does not match the healthcare innovation capital investment cycles. The venture capitalists (VCs) who provide most of the funds for important small health care entities typically have a cycle of 6-8 years while

the rule allows a ten year life for regulations that, during this period, potentially throttle VC investment for the very small entities that it seeks to protect.[6]

Ongoing, concurrent review will help to eliminate this problem

Although VC investments provide substantial capital, they are hardly flawless. Nevertheless, concurrent review that acknowledges their time horizon is important to healthcare productivity in other ways. For one, VCs' vision of successful innovations differs from others; consider, for example, the strong relationship between venture capital investments and the proliferation of patents they yield.[7] Then too, successful private sector investments are rapidly disseminated because the VCs must deploy their well-honed strategic and organizational skills to reach the scale needed to exit in an IPO or sale. Private sector investments also do not rely on public monies to fund successes or failures, and, if successful, pay taxes and fees, unlike public or most non-profit innovations.

Finally, private sector investment provokes competition by facilitating different ideas of how to accomplish system-wide goals. For example, HSS programs to fund integration of health care delivery through accountable care organizations and bundled care are worthy,[8] but their impact has been variable and remains uncertain.[9,10] Public sector innovations like these can benefit from competition with privately funded ventures with different visions and skill sets.

Concurrent Review of Regulations: COVID

The impact of concurrent review was apparent in the 2020 appraisal of regulations that could impede innovative responses to the shortages of traditional delivery sites caused by the COVID epidemic. It leveraged the important delivery innovations of telemedicine, retail medical clinics (RMCs), and ambulatory surgical centers by modifying restrictive regulations.

The impact of concurrent review spurred unprecedented VC investment in health care delivery innovations. Alternative care led in funds invested in the delivery space with, for example, a $175M investment in VillageMD, a community clinic model led by primary care M.D.s that ,in a collaboration with Walgreens, is providing innovations in the delivery of primary care in 500-700 neighborhood stores.[11]

Telemedicine. It has taken a pandemic to modify the regulations to bring telemedicine, which many long recognized as a positive technology for improving access to care, to the forefront.[12] The key regulatory barriers included inadequate reimbursement, restricted coverage, and onerous requirements for interstate medical licensure and hospital credentialing. Thus, the telemedicine firm Teladoc languished for years; but its revenues skyrocketed from $ .553 B in 2019 to $.867B for the third quarter of 2020 as these regulations were modified. Private Q1 2020 digital health VC funding grew to $3.6 billion, its highest-funded quarter.[13]

Retail Medical Clinics (RMCs) and Scope of Practice Regulation. RMCs, managed by firms such as CVS and Walmart, can offer a limited, but effective, menu of cost-controlled, quality assured services in convenient neighborhood settings.[14] They are often staffed by nurse practitioners (NPs) whose quality of care for a variety of chronic conditions and provision for access to primary care has long been recognized[15,16] especially in innovative settings, such as RMCs.[17,18,19] Uncertainty about revisions in the scope of practice of the NPs who could staff RMCs, as well as concerns about the cost of increased utilization,[20] are likely explanations for the long-time shortage of investment in RMCs.[21,22] The Department of Health & Human Services' (DHHS) new rules permitting expansion of scope of practice during COVID-19 significantly contributed to the increased use of NPs across the primary care landscape.[23]

Ambulatory Surgical Centers (ASCs) Settings .Similarly, when HHS reviewed the impact of the Physician Self-Referral (Stark) laws[24] that restricted physician interests in health care delivery entities and issued "safe harbor" revisions to protect various physician-owned ASCs and hospital/physician ASC joint ventures and investments, it created new opportunities for surgeries to be performed in less-costly, effective sites.[25] Private sector investors rapidly capitalized on the opportunity, in conjunction with physicians.

In response, (1) more surgeries were performed as outpatient procedures, (2) there was increased use of less-costly ambulatory surgical centers, and (3) administrative and overhead costs were reduced as surgeons maintained some ownership of practice.[26] After the change, United Healthcare, among other commercial insurers, allowed coverage for urgent care centers and ambulatory care clinics regardless of ownership.[27] Simultaneously, the number of urgent care centers continue to grow from 6,400 in 2014 to 8,100 in 2018,[28] at a CAGR of 6.07%, and to 8,650 in 2019 at a CAGR of 6.79%.[29]

Reverse Transfers. The absence of concurrent review has deterred the transfer to the U.S. of important global healthcare delivery innovations. Certificate-of-need (CON) regulation that requires a review of whether a new delivery site is "needed", is considered by some to have created no positive clinical effects and to have been captured by *status quo* organizations to deter investment in competitive organizations.[30,31]

The U.S. entry of innovative entities such as India's VC -backed cancer firm, Healthcare Global,[32] which improves cost and access through a hub and spoke model and yield or flexible pricing (differential prices depending on demand at a given time) has been deterred. Yield pricing increased utilization at off-peak times and thus decreased the average cost of the expensive hub's fixed radiology assets, while the low-cost, conveniently located hubs increased access.[33,34] Prevent Senior, a Brazilian VC- backed healthcare delivery firm, is another potential reverse transfer innovation that creatively provides vacations in its owned hotel facilities to patients who may otherwise frequent Emergency Rooms because they are lonely. This innovation enabled it to increase patient satisfaction and deliver better, less costly care.[35]

U.S. investments in helpful VC-backed, global innovations like these are deterred because of the hurdles State CONs could pose to the hub and spoke and hotel models and the difficult challenge of amending Medicare/Medicaid reimbursement rules to include yield pricing.

Concurrent Regulation

Regulatory review should scrutinize unintended consequences,[36] including an assessment of the extent to which a regulation poses barriers to meeting goals through innovation.[37] Policy vigilance requires continuous attentiveness or what we call concurrent review. The current reconceptualization of the barriers posed to innovation by the Stark Laws provides a good example of the consequences of the absence of ongoing review. The enactment of the new rules, scheduled for January 2021,[38] comes decades after the law's initiation and years after recognition of the unintended consequence of the law's prohibiting participation and investment by those closest to the goals for improved clinical outcomes. As CMS noted, "Overall this rule will result in better access and outcomes for patients by creating clearer paths for the providers that serve them to do so through enhanced coordinated care arrangements."[39]

Ongoing, or concurrent, review should not only assess the conditions under which a regulation fails to serve its original purpose(s) by suppressing innovations that might have contributed to improvements in the cost, quality, and access to health care. It should also consider instances where the regulation achieved its original goals and encouraged VC investment .[40] For example the antitrust shelter (42 C.F.R. § 1001.952(j) and the discount safe harbor, 42 C.F.R. § 1001.952(h),) regulations, which allow group purchasing organizations freedom to negotiate favorable pricing for their members, have sustained private investment.[41]

Conclusion

Private sector investment has led to important improvements in healthcare information technology, pharmaceuticals, and medical devices. Concurrent review could enable VCs to achieve similar results in health care delivery by stimulating investment in innovative sites and caregivers for cost-controlled, convenient health care delivery. [42,43,44]

Unfortunately, the ten year "sunset" clause for rules and regulations signals the private capital investors and innovators that the significant barriers they perceive are difficult to surmount and likely to be sustained. Concurrent review of regulation that assesses barriers to investment for delivery innovation is a key to increased policy-related success.

The Paris Climate Accord's "global stocktake" framework, which mandates the need to "pause and account for what has been achieved" to reach intended consequences, provides a model for health sector concurrent regulation assessment.[45] It is conducted in a comprehensive and facilitative manner, considering "mitigation, adaptation, and the means of implementation and support, in light of equity and the best

available science."[46,47] Observing and documenting private sector financing responses, or their absence, should be a regular feature of concurrent review as should scrutinizing investment in other industries and nations where VC investment has proliferated. Ongoing, or concurrent review, which rapidly considers if a regulation fails or succeeds in its original purpose(s), will stimulate much needed private sector investment in innovative health care delivery. Although concurrent assessment of a regulations can be time consuming, expensive and without consequence, reduction of barriers to private sector investment for delivery innovation is one key to achieving the important increased productivity growth in healthcare experienced in other brick and mortar service industries.[48] Significant private sector investment will be needed as the U.S. healthcare system works to recover from the devastation brought forth by COVID-19. Concurrent review can open up the doors to needed funding.

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[1] Securing Updated and Necessary Statutory Evaluations Timely, https://www.federalregister.gov/documents/2020/11/04/2020-23888/securing-updated-and-necessary-statutory-evaluations-timely

[2] https://www.bls.gov/lpc/hospitals_2013.htm; https://www.bls.gov/news.release/prin1.htm#:~:text=Long-term%20Labor%20Productivity%20Increases, 2.9%20percent%20in%20retail%20trade.&text=Amo; https://www.bls.gov/opub/ted/2020/labor-productivity-growth-in-retail-trade-in-2019-at-its-highest-since-1999.htm?view_full).

[3] Stigler, George (1915). "The Theory of Economic Regulation" (PDF). *Bell Journal of Economics and Management Science,* (Spring, 1971*)*. **2** (1): 3–21; Carpenter, Daniel; Moss, David A. (2014). "Preventing Regulatory Capture" . Cambridge University Press,2015)

[4]Modern Healthcare. **HHS finalizes plan to review and eliminate old regulations.** January 08, 2021 10:10 AM https://www.modernhealthcare.com/law-regulation/hhs-finalizes-plan-review-and-eliminate-old-regulations#:~:text=HHS%20on%20Friday%20finalized%20a,is%20not%20assessed%20will%20expire.&text=HHS%20would%20first%20decide%20whether,large%20number%20of%20small%20entities.

[5]Funk W. HHS Proposes to Sunset Regulations It Fails to Review Retrospectively, by William Funk. Yale Journao of Regulation. *December 1, 2020. https://www.yalejreg.com/nc/hhs-proposes-to-sunset-regulations-it-fails-to-review-retrospectively-by-william-funk/*

[6] Fleming JJ. The decline of venture capital investment in early-stage life sciences poses a challenge to continued innovation. Health Affairs, 2015:*34*(2), 271-276.

[7] Kortum S, Lerner J. Assessing the Contribution of Venture Capital to Innovation. Rand J Econ. 2000 Feb;31(4):674-692. doi:10.2307/2696354.

[8] Fisher, E. S. (2016). Medicare's bundled payment program for joint replacement: promise and peril?. *Jama*, *316*(12), 1262-1264.

[9] Gaynor M, Mostashari F, Ginsburg P. Making Health Care Markets Work: Competition Policy for Health Care. The Brookings Institution. 2017 Apr [cited 2019 Nov 1]. https://www.brookings.edu/wp-content/uploads/2017/04/gaynor-et-al-final-report-v11.pdf

[10]Fisher, E. S., Shortell, S. M., O'Malley, A. J., Fraze, T. K., Wood, A., Palm, M., ... & Meara, E. (2020). Financial Integration's Impact On Care Delivery And Payment Reforms: A Survey Of Hospitals And Physician Practices: Based on survey results, the study examines the impact of financial integration on care delivery and payment reforms among hospitals and physician practices. *Health Affairs*, *39*(8), 1302-1311.

[11] PYMNTS. VillageMD CEO: How The Walgreens Partnership Can Fix What's Broken In Primary Healthcare https://www.pymnts.com/healthcare/2020/villagemd-ceo-how-the-walgreens-partnership-can-fix-whats-broken-in-primary-healthcare/

[12] Rockwell, K. L., & Gilroy, A. S. (2020). Incorporating telemedicine as part of COVID-19 outbreak response systems. *Am J Manag Care*, *26*(4), 147-148.

[13] CMS. Trump Administration Finalizes Permanent Expansion of Medicare Telehealth Services and Improved Payment for Time Doctors Spend with Patients, https://www.cms.gov/newsroom/press-releases/trump-administration-finalizes-permanent-expansion-medicare-telehealth-services-and-improved-payment, December 1, 2020.

[14] Shrank, W. H., Krumme, A. A., Tong, A. Y., Spettell, C. M., Matlin, O. S., Sussman, A., ... & Choudhry, N. K. (2014). Quality of care at retail clinics for 3 common conditions. *Am J Manag Care*, *20*(10), 794-801.

[15] Kuo Y, Loresto F, Rounds L, Goodwin J. States with the Least Restrictive Public Policy Experienced the Largest Increase in Patients Seen by Nurse Practitioners. Health Aff. 2013; Jul 1;32(7):1236–1243. doi:10.1377/hlthaff.2013.0072.

[16] Horrocks, S., Anderson, E., & Salisbury, C. (2002). Systematic review of whether nurse practitioners working in primary care can provide equivalent care to doctors. *Bmj*, *324*(7341), 819-823.

[17] Corkery M, Gelles D, Sanger-Katz M. Walmart in Talks to Strengthen Ties to Health Insurer Humana. *The New York Times.* 2018 Mar 30 [cited 2019 Nov 1]. Available from: https://www.nytimes.com/2018/03/30/business/walmart-humana-merger.html.

[18] Carthon, J., M., B., Sammarco, T., Pancir, D., Chittams, J., & Nicely, K., W. (2017). Growth in retail-based clinics after nurse practitioner scope of practice reform. Nursing Outlook, 65, 195-201. https://doi.org/10.1016/j.outlook.2016.11.001

[19] Yang, B. K., Johantgen, M. E., Trinkoff, A. M., Idzik, S. R., Wince, J., & Tomlinson, C. (2020). State Nurse Practitioner Practice Regulations and US Health Care Delivery Outcomes: A Systematic Review. *Medical Care Research and Review*, 1077558719901216.

[20] Ashwood J, Gaynor M, Setodji C, Reid R, Weber E, Mehotra A. Retail Clinic Visits for Low-Acuity Conditions Increase Utilization and Spending. *Health Aff.* 2016: Mar 1;35(3). doi:10.1377/hlthaff.2015.0995.

[21] Carthon JMB, Sammarco T, Pancir D, Chittams J, Nicely KW. Growth in retail-based clinics after nurse practitioner scope of practice reform. Nursing outlook. 2017; *65*(2): 195-201.

[22] Kuo Y, Loresto F, Rounds L, Goodwin J. States with the Least Restrictive Public Policy Experienced the Largest Increase in Patients Seen by Nurse Practitioners. Health Aff. 2013; Jul 1;32(7):1236–1243. doi:10.1377/hlthaff.2013.0072

[23]American Association of Nurse Practitioners. Nurse Practitioner COVID-19 Survey, Executive Summary. https://www.aanp.org/practice/practice-related-research/research-reports/nurse-practitioner-covid-19-survey-2

[24] Centers for Medicare and Medicaid Services. Modernizing and Clarifying the Physician Self-Referral Regulations. CMS-1720-F federalregister.gov/d/2020-26140

[25]MEDPAC, Report to Congress. Ambulatory surgical center services: Assessing payment adequacy and updating payments MEDPAC, Ch. 5. In MEDPAC Report to Congress. 2018 Ambulatory Surgical Services Centers http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0

[26] Galetta, M. S., Makanji, H. S., Strony, J., Goyal, D. K., & Kurd, M. F. (2019). Changing reimbursement models and private equity ownership in spine surgery. *Annals of Translational Medicine*, *7*(Suppl 5). P.3

[27] UnitedHealthcare Inc. Member Resources. 2019 [cited 2019 Nov 1]. Available from: https://www.uhc.com/individual-and-family/member-resources/urgent-care
[28] Dolan S. How the growth of the urgent care industry business model is changing the healthcare market. *Business Insider*. 2019: Mar 18
[29] [29] CAGR data and computation by Jeffrey Cronin, HBS Baker Library, June 2020.
[30] Bailey, J. (2018). The effect of certificate of need laws on all-cause mortality. *Health services research*, *53*(1), 49-62.
[31] Conover, C. J., & Bailey, J. (2020). Certificate of need laws: a systematic review and cost-effectiveness analysis. *BMC health services research*, *20*(1), 1-29.
[32] https://www.business-standard.com/article/companies/healthcare-global-hospitals-looks-at-global-markets-for-next-growth-phase-118112200889_1.html
[33] Lieberman, W. From yield management to price optimization: Lessons learned. *J Revenue Pricing Manag* **10,** 40–43 (2011). https://doi.org/10.1057/rpm.2010.44
[34] Herzlinger, R., Ghorawat, A., Krishnan, M., & Saggi, N. (2014). Hub and spoke, healthcare global, and additional focused factory models for cancer care. *Harvard Business School Case 313*, *30*.
[35] Herzlinger, R. E., Malik, A. M., & Zogbi, P. (2017). Prevent Senior: A New Paradigm for Growth in the Health Care Sector?.
[36] National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, Brief 1: Overview of Policy Evaluation. https://www.cdc.gov/injury/pdfs/policy/Brief%201-a.pdf
[37] Oliver, K., Lorenc, T., Tinkler, J. *et al.* Understanding the unintended consequences of public health policies: the views of policymakers and evaluators. *BMC Public Health* **19,** 1057 (2019). https://doi.org/10.1186/s12889-019-7389-6
[38] Modernizing and Clarifying the Physician Self-Referral Regulations Final Rule (CMS-1720-F), Nov 20, 2020. https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-final-rule-cms-1720-f
[39] Ibid.
[40] Roca, J. B., & O'Sullivan, E. (2020). The role of regulators in mitigating uncertainty within the Valley of Death. *Technovation*, 102157.
[41] Jones, J. Member-Owned Group Purchasing Organizations: What You Need to Know. Martindale. https://www.martindale.com/venture-capital/article_Pepper-Hamilton-LLP_144634.htm
[42] Rosenthal E. That Beloved Hospital? It's Driving Up Health Care Costs. The New York Times. 2019 Sep 1 [cited 2019 Nov 1]. Available from: https://www.nytimes.com/2019/09/01/opinion/hospital-spending.html.
[43] Papanicolas I, Woskie L, Jha A. Health Care Spending in the United States and Other High-Income Countries. JAMA. 2018; Mar 13;319(10):1024-1039.
[44] Minemeyer P. In a blow to HHS, Supreme Court sides with hospitals in legal battle over DSH payments. Fierce Healthcare. 2019; Jun 3 [cited 2019 Nov 1]. Available from: https://www.fiercehealthcare.com/hospitals-health-systems/a-blow-to-hhs-supreme-court-sides-hospitals-legal-battle-over-dsh-payments.
[45]Northrop, E. Mogelgaad, K. Thwaites, J. INSIDER: Designing the Global Stocktake under the Paris Agreement: The Catalyst for Climate Action. World Resources Institute. May 1, 2017. https://www.wri.org/blog/2017/05/insider-designing-global-stocktake-under-paris-agreement-catalyst-climate-action

[46] United Nations Climate Change. Global Stocktake Referred to in Article 14 of the Paris Agreement. https://unfccc.int/topics/science/workstreams/global-stocktake-referred-to-in-article-14-of-the-paris-agreement

[47] Schwartz, J. A. (2010). 52 Experiments with regulatory review: The political and economic inputs into state rulemakings. Institute for Policy Integrity, New York University School of Law.