



# How the Next Administration Can Lower Drug Prices

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# Introduction and summary

Lowering prescription drug prices continues to be a top health care priority for Americans.<sup>1</sup> The American people want the government to take significant, meaningful actions to lower the prices of prescription drugs, and the coronavirus pandemic has further underscored the importance of ensuring that essential medicines are priced affordably—for both the health care system and individuals. As a number of treatments for the virus have emerged and clinical trials for COVID-19 vaccines continue to advance, there is a growing danger that these lifesaving treatments could have price tags that put them out of reach for millions of Americans.<sup>2</sup>

Action to lower the prices of prescription drugs is also an issue of health equity. Black Americans are among the communities facing disproportionate impacts of COVID-19; due to systemic racism, they face higher incidence of preexisting conditions and poorer health outcomes than white Americans from numerous chronic health conditions, including diabetes and heart disease,<sup>3</sup> that lead to greater risks from the coronavirus and are treated with prescription drugs that have sky-high drug prices. For instance, the price of a single vial of Humalog, a commonly used insulin, has increased by more than 1,200 percent since its debut in 1996.<sup>4</sup>

Congress must move to enact comprehensive prescription drug pricing reforms, such as H.R. 3, which the U.S. House of Representatives approved in late 2019.<sup>5</sup> But the next administration need not wait for congressional action. Federal law currently grants the president administrative authority to take targeted actions to ensure public access to drugs with out-of-reach high prices or inadequate stockpiles.

The first section of this report provides background on drug companies' monopoly power and how taxpayer money supports drug research and development. The following section outlines how the next president should use his administrative authorities to ensure access to COVID-19 treatments and future vaccines, as well as other drugs that are essential to high-risk populations and drugs whose prices drug companies continue to raise during the pandemic. While there are likely hundreds of other drugs with

excessive prices, these drugs should be the priority for action given the public health crisis. The final sections of this report outline ways in which the next administration can think beyond the COVID-19 crisis and test different ways for Medicare to pay for prescription drugs.

# Background

Prices for prescription drugs have consistently risen throughout the past decades. A recent study by the University of Pittsburgh’s Center for Pharmaceutical Policy and Prescribing found that from 2007 to 2018, list prices for prescription drugs increased by 9.1 percent per year.<sup>6</sup> The study also found that even when accounting for discounts provided to health insurance programs, the net price of prescription drugs increased by 4.5 percent per year, a rate far greater than average annual inflation.<sup>7</sup> This trend has continued even during the coronavirus crisis. So far in 2020, drug companies have raised the prices of more than 800 drugs, with the prices of more than 40 drugs being increased in July alone.<sup>8</sup>

Understandably, these price increases have caused prescription drug spending to increase dramatically as well. Between 1960 and 2017, real per capita prescription drug spending increased from \$90 to \$1,025—more than a 1,000 percent increase.<sup>9</sup> For comparison, the cumulative change in inflation during the same time period was 728.1 percent.<sup>10</sup> Prescription drug spending accounts for around 10 percent of the National Health Expenditures estimates.<sup>11</sup> Notably, however, this estimate does not include physician-administered drugs, which are more likely to be costly biologics—drugs made from living cells or tissues.<sup>12</sup> These drugs add significant additional spending.<sup>13</sup> In 2017, prescription drug retail spending reached \$333 billion; this number also excludes physician-administered drugs.<sup>14</sup>

Policymakers must consider drugs’ affordability as well as their price. Around 60 percent of U.S. adults take at least one prescription drug each year, and without policies to ensure affordability, they may do so in a way that makes these drugs less effective. In 2017, the most recent year for which the Centers for Disease Control and Prevention (CDC) survey is available, more than 10 percent of the U.S. population reported rationing drugs to help address affordability,<sup>15</sup> and this rationing can be lethal.<sup>16</sup> Policymakers working to reduce drug prices must center the goal of making drugs affordable for the people who need them to live healthy lives.

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## Drug companies' monopoly power

There are a number of reasons why patients and health care payers—including the Medicare program—pay such excessive prices for drugs. The United States' patent system and market exclusivity rules shield drug manufacturers from normal market competition, giving these corporations significantly greater bargaining power than health payers. In an attempt to promote pharmaceutical companies' innovation, the federal government temporarily gives the companies market exclusivity—essentially, a government-granted monopoly for selling a drug.<sup>17</sup> This exclusivity period generally ranges from five years to seven years, depending on the type of drug developed.<sup>18</sup> Some notable exceptions to this range are two generic drug exclusivities, which only receive 180 days of exclusivity, and biologics, which generally receive 12 years of exclusivity.<sup>19</sup>

In addition to market exclusivity periods, prescription drug companies are known to manipulate federal patent law to extend their monopoly power. For example, drug companies engage in practices such as evergreening, in which they make a minor modification to a drug and receive a new patent.<sup>20</sup> Another example is patent thickets, where drug manufacturers establish “a dense web of overlapping intellectual property rights that a company must hack its way through” before being able to compete with them.<sup>21</sup>

A final manipulation of drug exclusivity rules is parking, in which a generic drug-maker receives exclusivity for challenging a branded drug patent but delays having the drug approved.\* Due to a provision of federal law meant to give generic manufacturers a short period of “co-exclusivity,” this can prevent other manufacturers from selling their own generic drugs.<sup>22</sup> In particular, this becomes an issue when generic manufacturers come to an agreement with the brand manufacturer to delay final approval of their drug, artificially extending the brand drug's exclusivity.<sup>23</sup>

By establishing overlapping patents and making minor changes to drugs in order to maintain a patent, pharmaceutical companies create lengthy periods in which they have no competitors for a given drug. Research shows that this keeps prices high.<sup>24</sup>

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## Taxpayer support for drug research and development

Taxpayers support drug corporations in a number of ways. First, taxpayers fund the basic research that underpins many drugs.<sup>25</sup> In fact, a 2017 study found that every drug approved by the Food and Drug Administration (FDA) between 2010

and 2016 was built on research funded by the National Institutes of Health (NIH), which is a government agency supported by taxpayer funds.<sup>26</sup> A notable example of this is Sovaldi, a drug that cures Hepatitis C. When the drug was first introduced, Gilead Sciences charged a list price of \$84,000 for a course of treatment.<sup>27</sup> The NIH grants played a key role in the initial development of the drug by Pharmasset,<sup>28</sup> the drug company that developed the drug before selling it to Gilead.

In addition to the NIH, the Biomedical Advanced Research and Development Authority (BARDA) works to “transition . . . medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development.”<sup>29</sup> The agency was established by the federal government in 2006 in response to the 2001 anthrax attacks and has awarded billions of dollars in funds to drug companies and public universities for research.<sup>30</sup> More recently, BARDA has awarded billions of dollars to drug companies to develop COVID-19 vaccines and treatments.<sup>31</sup>

Other federal departments fund prescription drug research as well. The U.S. Department of Defense has awarded around \$16 billion in grants through the Congressionally Directed Medical Research Programs since the latter’s inception in 1992—many of which have gone to prescription drug companies—as well as through the U.S. Army Medical Research Institute of Infectious Diseases.<sup>32</sup> The U.S. Department of Energy also provides support, using its facilities to process information such as protein structures that help lead to drug discoveries; for example, these facilities have led to the discovery of new drugs to treat melanoma.<sup>33</sup>

Second, the costs of a drug company’s additional research are offset in part by tax credits. Manufacturers can seek a tax credit for up to 20 percent of manufacturing companies’ “qualified research expenses” above a base amount.<sup>34</sup> Pharmaceutical companies receive further tax credits for research and development on drugs for rare diseases; in 2016, this resulted in \$1.76 billion in tax incentives to drug companies.<sup>35</sup> The credit was reduced in 2016 but remains at a hearty 25 percent of qualified research expenses.<sup>36</sup>

Third, drug companies can deduct the cost of advertising and marketing from their federal taxes.<sup>37</sup> This provision of law allowed U.S. prescription drug manufacturers to spend \$6 billion on advertisements for drugs in 2016 and then deduct those expenses from their taxes.<sup>38</sup>

Fourth, taxpayers support drug companies again not only when they pay the excessive prices for drugs they need, but also each time Medicare or other government health care programs pay for a prescription drug.

# Administrative actions to address the drug industry’s monopoly power

The monopoly power of drug manufacturers is not absolute, and federal law includes important safeguards that allow the government to intervene when a manufacturer’s actions are inconsistent with public health needs. Two federal laws, the Bayh-Dole Act and U.S. Code Title 28, Section 1498, can be used to ensure widespread, affordable access to essential medicines.

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## Bayh-Dole Act

The Bayh-Dole Act allows nongovernmental entities, including private businesses and nonprofit organizations, to retain the intellectual property rights to discoveries and inventions developed through federally funded research.<sup>39</sup> Before the law’s passage in 1980, the United States owned the rights to any intellectual property developed from federally funded research and development and generally shared the intellectual property through nonexclusive licenses.<sup>40</sup> Pharmaceutical companies were less likely to develop these products, however, given that their competitors also had access to these discoveries. After the passage of the Bayh-Dole Act, entities such as universities that receive federal grants for their research can sell or license their inventions, including to pharmaceutical companies.

These license agreements are not absolute; the federal government may exercise its so-called march-in rights to license patents that resulted from federally funded research but that are now owned by drug companies. The federal government may “march in” when a drug company has not achieved “practical application” of the research—meaning that the research’s benefits are not “available to the public on reasonable terms.”<sup>41</sup> March-in rights also apply when “action is necessary to alleviate health or safety needs.”<sup>42</sup> Thus, if a drug company is not charging a reasonable price for a drug, or if its pricing harms public health by substantially restricting access to the drug, the federal government is well within its rights to ensure the availability of cheaper generic versions.

Today, there are two pharmaceutical treatments for COVID-19. One is a widely used steroid, dexamethasone, and the other is remdesivir.<sup>43</sup> Remdesivir was developed through federally funded research for use against Ebola: The CDC and Department of Defense contributed more than \$70 million in funding for the development of the drug, and Gilead is now charging more than \$3,100 for the drug for a typical COVID-19 patient with private health insurance.<sup>44</sup> Gilead has been unable to keep up with the domestic and global demand for the drug, leading to shortages throughout the United States medical system.<sup>45</sup> The health risk posed by this drug being unaffordable or insufficiently produced meets the requirements for the government to exercise its march-in rights.

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## Government patent use

Another federal law—U.S Code Title 28, Section 1498—allows the federal government to issue licenses for patented technology, even without the patent holder’s consent, as long as the government pays “reasonable and entire compensation” to the patent holder.<sup>46</sup> So-called government patent use allows the government to enter into licenses with additional drug manufacturers to produce a drug, which would increase capacity and lower the price of the drug. This is particularly critical with COVID-19, as there will be high demand for any drug shown to be effective in treating the disease and even higher demand for an eventual vaccine.

In cases in which the federal government has a co-ownership interest in a drug’s patents—as is likely the case for the drug remdesivir—the government would only pay compensation related to the patents held exclusively by the drug company.<sup>47</sup>

The compulsory licensing authority under Section 1498 has not been used with regard to prescription drugs in recent years,<sup>48</sup> but its use has been threatened to great effect. In 2001, when the United States faced threats of anthrax attacks, Bayer attempted to charge the normal price for ciprofloxacin, the best available treatment for anthrax at the time.<sup>49</sup> The secretary of health and human services threatened to use compulsory licensing authority on the drug, which led Bayer to reduce the price.<sup>50</sup>

In addition, drug companies continue to raise prices on existing drugs during this pandemic,<sup>51</sup> so there may be additional need to exercise these rights for other critically needed drugs. For example, uncontrolled diabetes is associated with higher risk of complications from COVID-19.<sup>52</sup> In the last decade, the list prices of several

common types of insulin tripled, even though the drugs themselves have remained unchanged.<sup>53</sup> A survey by T1International found that more than 1 in 4 Americans with diabetes have rationed insulin in the past year, a response to unaffordable treatment that can be deadly.<sup>54</sup> As the pandemic rages on, ensuring that people with diabetes have access to insulin is a critical step in minimizing long-term health consequences and loss of life.

## Drugs to prioritize for administrative action

The president must prioritize administrative actions to lower the prices of treatments and future vaccines for COVID-19. As discussed above, many of the existing drugs to treat COVID-19 are built on discoveries made through federally funded research, and the impacts that COVID-19 has on public health, economic indicators, and national security all provide the strongest possible basis for federal intervention to ensure affordability and access.

The second factor that should be considered is a drug's impact for populations at higher risk of complications from COVID-19. People with preexisting conditions, disabled people, and older adults have a higher risk of death or long-term impact from COVID-19,<sup>55</sup> and due to centuries of systemic racism, people of color—Black people in particular—are more likely to have preexisting conditions.<sup>56</sup> Critical drugs for these populations—for example, insulin for diabetics and drugs such as Truvada, for people with HIV whose weakened immune systems and higher risk of complications may make them more susceptible to viruses such as the coronavirus—are equally important targets for the president to ensure affordability, in terms of their impact on COVID-19 health outcomes and health equity.

Finally, drugs whose prices have been raised by pharmaceutical companies during the pandemic should also be among those considered for early administrative actions. The coronavirus crisis has had unprecedented impacts on health outcomes and economic well-being. Raising prescription drug prices is especially egregious during a global health crisis, as millions of Americans have lost their jobs and employer-sponsored health insurance. At a time when prescription drug access is especially critical and economic factors make prescription drugs less affordable, pharmaceutical companies should not compound that lack of access. The president has the authority to intervene with these drugs as well, not only the drugs most directly related to COVID-19 health outcomes.

# Administrative actions to lower the prices Medicare pays for drugs

Even as Medicare grapples with the impacts that the ongoing COVID-19 pandemic has had on its beneficiaries, the program continues to provide prescription drug benefits for more than 45 million people, paying for nearly 3,500 unique drugs, the vast majority of which are not directly related to the virus.<sup>57</sup> Simultaneous with the actions described above, the next administration should test new ways to pay for expensive Medicare-covered drugs and make additional information available about the prices of key Medicare drugs.

## How does Medicare pay for drugs?

Medicare is a public health insurance program for people ages 65 years and older and certain younger disabled people, as well as people with end-stage renal disease.<sup>58</sup> The program pays for prescription drugs in a variety of ways. Most drugs are covered and paid for through Medicare Part D, the program's retail prescription drug benefit.<sup>59</sup> This benefit is administered by either a Medicare prescription drug plan (PDP) or through a Medicare Advantage plan that administers both the beneficiary's medical and drug benefits.<sup>60</sup> Because the Medicare program is prohibited by law from directly negotiating the prices of prescription drugs, these plans negotiate discounts with pharmaceutical companies in the same way that private insurance companies do for people with employer-sponsored insurance.<sup>61</sup> These negotiations can lead to discounts for the PDPs, through direct and indirect remuneration (DIR) fees. DIR fees are discounts—often in the form of rebates paid by the manufacturer—that lower the final price paid by the PDP.<sup>62</sup> Medicare should receive all DIR payments, but PDPs and manufacturers structure these arrangements to avoid Medicare's technical definition of DIR so that the discount remains with the PDP.<sup>63</sup>

While Part D pays for most drugs that Medicare beneficiaries receive, around 25 percent of Medicare prescription drug spending is through Medicare Part B.<sup>64</sup> These drugs are typically administered by a physician or other health professional, rather than taken by the patient at home.<sup>65</sup> Payments for Part B drugs are not negotiated by plans, like Part D drugs. Instead, Medicare pays 100 percent of the average sales price (ASP) plus a 6 percent add-on to providers, which is the average of prices charged by the drugmaker in the commercial market, including discounts and rebates.<sup>66</sup> The providers administering these drugs receive this payment directly, regardless of the price the provider paid for the drug.<sup>67</sup>

The Center for Medicare and Medicaid Innovation (CMMI) tests the effects of various payment and delivery system models on Medicare and Medicaid program expenditures as well as the quality of care under those programs.<sup>68</sup> As part of these testing models, the CMMI may waive provisions of federal law surrounding these programs, although there is far greater flexibility in which Medicare provisions may be waived than in Medicaid.<sup>69</sup> The following section discusses how the next administration should use its authority through the CMMI to test various ways to lower the prices of both Part B and Part D drugs.

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## Lowering the price of physician-administered drugs

The next administration should revive the Part B demonstration that the Obama administration proposed in 2016.<sup>70</sup> The demonstration would have taken place in two phases: The first would have changed the ASP add-on for Part B drugs from 6 percent to 2.5 percent plus a flat fee, and the second would have implemented a variety of value-based purchasing tools into the Medicare program.<sup>71</sup> The rule was eventually withdrawn after the 2016 election in the face of criticism from pharmaceutical companies and members of Congress, preventing the CMMI from conducting these tests.<sup>72</sup>

There is good reason to believe that the ASP add-on reform in particular would have been helpful. Because the current system pays providers 6 percent of a drug's ASP, providers are incentivized to choose more expensive drugs for patients, even if the more expensive drug provides no additional clinical benefit. Because providers' payments are dependent on the cost, rather than the quality of the care, the providers receive more money for ordering more expensive drugs. Switching to a flat fee would help incentivize providers to choose the appropriate drug rather than the one that will result in a higher payout. Additionally, this policy would encourage drug manufacturers to lower their prices as providers no longer prescribe their more expensive drugs.

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## Lowering the price of Medicare Part D drugs

In addition to the Part B reforms discussed above, the next president will have many opportunities to reduce the prices of drug purchased through Part D of the Medicare program. These drugs comprise the majority of Medicare drug spending, and research shows the United States pays more for these drugs than its peer nations, even after accounting for discounts the program receives.<sup>73</sup> Part D drug prices are negotiated by private plans that administer the prescription drug benefit due to the noninterference clause, which prohibits direct negotiations by the Medicare program.<sup>74</sup> As with Part B, the CMMI's authority allows for the waiving of this provision, allowing for the CMMI to test the impact of interventions on pricing.

One important potential demonstration is reference pricing—establishing a single price across a group of drugs with similar characteristics.<sup>75</sup> Reference pricing can also refer to establishing a price for a drug based on an external benchmark. In a recent executive order, President Trump directed the secretary of health and human services to move forward with a demonstration to test how Medicare could pay for physician-administered drugs based on the price paid in a variety of other nations.<sup>76</sup> The same order also stated that the secretary should, in the future, “take appropriate steps to develop” a similar proposal for Part D drugs.<sup>77</sup>

This executive order is not a substitute for decisive, binding regulatory action. It simply directs the secretary to pursue rulemaking, but there is no guarantee when rulemaking would occur. Moreover, even if there is future rulemaking, the order leaves key terms undefined and punts critical decisions to the secretary. Instead of issuing unnecessary, nonbinding executive actions, the next administration should immediately undertake notice-and-comment rulemaking that targets the most expensive drugs and ensures patients benefit from lower drug prices.

The president should be prepared for backlash to these reforms. The pharmaceutical industry fiercely opposes any form of reference pricing due to its efficacy at reducing prescription drug prices. Multiple reviews of reference pricing affirm this. For example, a 2017 evaluation of the Reta Trust, a national association of 55 Catholic organizations that purchases health coverage for its employees, found that reference pricing was associated with a 13.9 percent lower price paid per prescription.<sup>78</sup> Similarly, an evaluation of Arkansas' state employee plan's experiment with reference pricing found that the net plan cost for proton-pump inhibitors fell by slightly less than 50 percent, despite essentially unchanged utilization by members.<sup>79</sup> Importantly, patient copayments per claim fell over the same period.<sup>80</sup>

Lastly, the CMS should consider ways to change the definition of DIR payments so that Medicare receives the discounts negotiated by the PDP. While a DIR structure can lower premiums because the PDPs have lower costs through these negotiated discounts, these arrangements shift costs to beneficiaries, whose cost-sharing for high priced drugs is based on the list price of the drug before any DIR fees are negotiated. This structure gives manufacturers yet another incentive to keep list prices high, because they can simply negotiate significant discounts with PDPs.

# Other HHS actions to encourage innovation and lower drug spending

In addition to actions to break the monopoly power of the drug industry and lower prices paid by Medicare, the next president will have the ability to lower prices through the U.S. Department of Health and Human Services (HHS). By recruiting scientists who perform the research underpinning drug development and reducing the opportunity for pharmacy benefit managers to overcharge, the next president can take additional action to lower drug prices and improve public health.

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## Recruiting scientists under the 21st Century Cures Act

There are two primary roles the federal government plays in developing drugs: funding research at academic institutions and performing the research itself through institutions such as the NIH. The latter of these relies on the government being able to recruit and retain a workforce of skilled researchers. Unfortunately, there is a documented trend of various agencies under HHS being unable to recruit the scientific workforce necessary.<sup>81</sup>

In response to this trend, Congress passed the 21st Century Cures Act in late 2016.<sup>82</sup> Among many other issues, the law quadrupled the number of positions in the Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service, a program that allows for government scientists to receive pay higher than what is typically allowed under federal law.<sup>83</sup> The law increased the salary cap for members of the program from \$219,200 to \$400,000.<sup>84</sup> Despite this legislative change, however, an audit by the Government Accountability Office found that while HHS has issued the regulations relevant to the law, the department has not begun using its new authority to recruit scientists.

Studies show that the basic research that leads to true innovation in the pharmaceutical industry is led by federally funded and federally performed research.<sup>85</sup> Contrary to what drug manufacturers assert, bolstering the ability of the federal government to perform this research is how innovative new drugs are developed.

By failing to use its authority to recruit new scientists, HHS is failing to uphold its mission to “[foster] sound, sustained advances in the sciences underlying medicine, public health, and social services.”<sup>86</sup> The next administration should capitalize on the opportunity that the 21st Century Cures Act has presented and work to ensure that HHS has a strong scientific workforce throughout its agencies.

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## Lowering drug spending in ACA marketplace plans

Another opportunity for HHS to help reduce drug spending is through the Affordable Care Act’s (ACA) medical loss ratio (MLR) provision. An MLR is essentially the proportion of revenue spent by an insurance company on medical claims and other efforts to improve the quality of care.<sup>87</sup> Under the ACA, insurance companies are required to maintain MLRs of 80 percent or 85 percent, depending on the type of insurer.<sup>88</sup>

As part of the implementation of the law, HHS is required to issue regulations establishing which expenditures by health insurers are considered medical claims. In making these determinations, HHS can significantly affect spending; if an expense is changed to be considered an administrative—rather than medical—expenditure, health insurers would have an additional incentive to minimize spending, in order to leave as much additional revenue for profit and salaries.

In particular, HHS should issue a rule establishing that spread pricing is not considered a medical expenditure for the purposes of MLR calculation. Spread pricing is the practice by pharmaceutical benefit managers (PBMs) of charging a health insurer more than the cost of a drug and retaining the difference.<sup>89</sup> The practice drives up costs for prescription drugs—and premiums—without any accompanying benefit; the extra money serves solely as profit for PBM companies.

Many states have worked to limit or ban the practice. One example is Massachusetts, which instead requires PBMs to charge health insurers the amount paid to pharmacies and a set administrative fee of \$10.02.<sup>90</sup> By doing so, Massachusetts has been able to reduce prescription drug spending without affecting patients’ access to medicines. This is especially true if PBM reimbursement is done through a set administrative fee; if reimbursement is done through a percentage of drug costs, PBMs would be encouraged to prioritize more expensive medicines in their formularies. The CMS has also banned spread pricing for Medicaid-managed care plan PBMs,<sup>91</sup> and this approach should now be expanded to ACA-regulated health plans.

# Conclusion

The next president has a number of administrative tools to reduce the price of prescription drugs. Doing so remains a top priority for voters and has become even more critical given COVID-19 and the racial inequities accentuated by the pandemic. Actions related to the COVID-19 pandemic should be among the top priorities for the next administration when assessing which drugs to target first. The actions outlined in this report do not replace the need for comprehensive drug pricing reform legislation, but they will help lower prices for critical drugs and send a clear signal to drug companies that the public will no longer continue to subsidize the industry at the expense of public health.

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*\* Correction, September 17, 2020: This report has been updated to clarify the definition of parking.*

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