

THE BIDEN ADMINISTRATION

MUST ENSURE THE

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The Affordable Care Act's (ACA) contraceptive coverage requirement—the provision that guarantees no-cost coverage of the full range of birth control methods—has significantly expanded access to birth control. As of fall 2020, because of this requirement, 64.3 million women¹ had insurance coverage that includes contraception without cost-sharing.²

This coverage has translated into significant benefits to people's economic security, health, and well-being. Without out-of-pocket costs as a barrier to preventive services, people are better able to access the care they need. Research has shown that the contraceptive coverage requirement has allowed some women to use prescription birth control for the first time and others to use more effective, longer acting-but more expensivemethods of birth control.³ And the coverage has had an outsized impact on individuals shouldering the heaviest burden of our nation's health inequities, especially during an economic crisis that has taken a disproportionate toll on women, and particularly on women of color and low-income women.4

Despite the enormous gains of the contraceptive coverage requirement, not everyone is receiving the coverage they are guaranteed by law. The National Women's Law Center continues to hear reports of violations among insurance plans that should be covering birth control without outof-pocket costs. The Law Center operates a nationwide hotline, CoverHer, which people can contact when they face problems accessing birth control coverage. Through this hotline, the Law Center continues to receive reports from people whose insurance plans are not complying with the law.

SPECIFICALLY, THE NATIONAL OMEN'S LAW CENTER HAS **IDENTIFIED THE FOLLOWING THREE TRENDS:**

- Plans are denying coverage for the specific contraceptive product needed, and do not have the required cost-sharing exceptions process;
- Plans are still failing to cover the services associated with birth control without out-of-pocket costs; and,
- Plans are failing to provide coverage of newly approved methods.

THE COVER HER **HOTLINE AND RESOURCES**

Since the contraceptive coverage requirement first went into effect in August 2012, the Law Center has been assisting people who are facing challenges securing no-cost birth control. The Law Center's CoverHer hotline and associated website (www. coverher.org) provide a way for people to get individualized assistance, information, and resources. Over the last nine years, nearly 7,700 people have contacted CoverHer from every state and Washington, D.C., sharing the challenges they face securing cost-free contraception and seeking advice for how to navigate the byzantine insurance, provider, and pharmaceutical systems. At the same time, CoverHer's user-friendly resources have enabled thousands more to take action to resolve their own problems. The reports received by CoverHer reflect immeasurable hours of time and stress for people to access what should be seamless, cost-free coverage.

The Law Center tracks the problems faced by women who contact CoverHer and has leveraged lessons learned through the hotline to inform and strengthen its efforts to ensure compliance with the ACA's contraceptive coverage requirement. In Spring 2015, the Law Center issued a report on health plan violations of the Affordable Care Act's contraceptive coverage requirement, which drew on CoverHer learnings and an in-depth review of health plan documents from across the country. Partly in response to these and other reports of violations, federal agencies issued new guidance in May 2015 to ensure that plans and issuers provide the coverage required by the law. Following the release of this guidance, many health plans updated their coverage. The Law Center continues to push for compliance and enforcement at the federal level based on CoverHer learnings. At the same time, the Law Center works with state partners and insurance commissioners to improve implementation, oversight, and enforcement at the state level.

These violations leave people to pay out of pocket for the birth control they need, push them into using a method that is not right for them because of cost, or cause them to forego contraception altogether. These non-compliant plans are reinstating the very barriers to contraception that the ACA's preventive services provision sought to remedy.

The federal agencies that oversee the ACA contraceptive coverage requirement must take action to ensure plan compliance with the law and guarantee that the promise of the contraceptive coverage requirement is met for everyone. Due in part to a lack of enforcement from federal and state agencies during the last four years, insurers are skirting the contraceptive coverage requirement and facing few repercussions. At the same time, insurers and federal and state agencies have not been proactive in ensuring that the requirement and plan coverage tracks new developments in contraceptive methods. This has left a significant number of people without the coverage to which they are legally entitled.

Among other actions, the Departments of Health and Human Services, Department of Labor, and the Treasury (the Departments) must issue guidance to respond to the problems identified in this report; reinvigorate the agencies' enforcement role and enforce the law as needed against noncompliant plans; monitor coverage trends and continue to issue guidance to respond to trends in noncompliance; and conduct a public awareness campaign about the contraceptive coverage requirement.

Strong leadership at the federal level can make a difference. In 2015, in response to documented problems of insurance plan noncompliance with the ACA's contraceptive coverage requirement, the Departments took action.5 The guidance issued by the Departments prompted many insurance plans to change their problematic policies— dramatically improving women's access to birth control.⁶ That leadership is needed again, to ensure that the contraceptive coverage requirement is working for everyone who needs it.

THE BIDEN **ADMINISTRATION SHOULD ALSO RESCIND HARMFUL TRUMP ADMINISTRATION EXEMPTIONS**

People continue to report to CoverHer that they are unable to obtain no-cost coverage of birth control because of their employer's or university's religious or moral objections to it. While this report focuses on compliance problems in health plans where no religious or moral objection to coverage exists, the fact remains that hundreds of thousands of people do not have birth control coverage because of sweeping exemptions put in place by the Trump administration. People who have been denied coverage of birth control often share their frustration and concern and are confused about how they can access or afford care without insurance coverage. The Biden administration must rescind the exemptions created by the Trump administration and issue new regulations to ensure everyone can get birth control coverage no matter where they work or go to school.

THE AFFORABLE CARE ACT'S

Contraceptive Coverage Requirement

The ACA's contraceptive coverage requirement is part of the Affordable Care Act's preventive health services provision, which is designed to enable individuals to avoid preventable conditions and improve health overall by increasing access to preventive care and screenings. The contraceptive coverage requirement specifies that plans must cover "the full range of Food and Drug Administrationapproved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity."7 Plans governed by the requirement must ensure that:

ALL FDA-APPROVED METHODS OF BIRTH CONTROL ARE COVERED WITHOUT OUT-OF-POCKET COSTS

The current Women's Preventive Services Guidelines, adopted by HHS's Health Resources and Services Administration (HRSA), are clear that plans must cover the full range of FDA-approved female-controlled contraceptives "and additional methods identified by the FDA."8 The HRSA guidelines explicitly list 18 different methods, based on the Food and Drug Administration (FDA) Birth Control Chart. Federal guidance also references the FDA's Birth Control Chart for further explanation of the required 18 methods.9 Federal guidance clarifies that under the contraceptive coverage requirement, plans and issuers "must cover without cost sharing at least one form of contraception in each of the methods."10

ALL BIRTH CONTROL-RELATED SERVICES ARE COVERED WITHOUT **OUT-OF-POCKET COSTS**

The services related to birth control—such as office visits, counseling, or medical services related to a sterilization procedure or insertion of a birth control method—must also be covered without cost-sharing. Other related services, such as follow-up visits, management of side effects, counseling for continued adherence, and device removal, must also be covered without cost-sharing.¹¹

ANY MEDICAL MANAGEMENT MUST BE "REASONABLE" AND LIMITED

Insurance companies are allowed to use "reasonable medical management techniques" to determine the "frequency, method, treatment, or setting for which a recommended preventive service will be available without cost sharing requirements to the extent not specified in a recommendation or guideline."12 But those medical management techniques are limited. For example, federal guidance has made clear that allowed "reasonable medical management techniques" include imposing out-of-pocket costs when a preventive service is accessed at an outof-network provider or imposing out-of-pocket costs on a branded drug when the insurance company covers an available generic equivalent without cost-sharing. But plans cannot, for example, require someone to try and fail

a contraceptive in one method category before covering a different contraceptive method (e.g., try and fail using a vaginal ring before covering a hormonal intrauterine device (IUD).)¹³

THERE MUST BE AN "EXCEPTIONS PROCESS" SO THAT A PERSON CAN GET NO-COST COVERAGE OF THE PARTICULAR BIRTH CONTROL PRODUCT THEY NEED

Federal guidance makes clear that when someone needs a specific contraceptive product within a method category, insurance companies must have a process in place to waive cost-sharing if that contraceptive is not typically covered cost-free.¹⁴ Access to the specific product a

person and their provider determine is right for them is incredibly important for contraception. Without access to the chosen product, contraindications or intolerable side effects to other products can force someone to use an entirely different contraceptive method, which is often less effective than their chosen method, or can lead to foregoing contraception entirely. The cost-sharing exceptions process must be "easily accessible, transparent...sufficiently expedient...[and] not unduly burdensome on the individual or a provider." The exceptions process must also defer to the provider's recommendation for that product—the insurer cannot overrule this determination. The federal guidance suggests issuers use the Medicare Part D exceptions form as a basis for the contraceptive cost-sharing exceptions process.



Violations of the **ACA Birth Control Requirement**

REPORTED TO THE LAW CENTER IN 2020 AND 2021

The insurance coverage violations detailed below were reported to the Law Center's CoverHer hotline between January 2020 and July 2021. Where CoverHer contacts provided their home state, age, the name of their insurance company or pharmacy benefits manager, or their source of coverage (marketplace or employer), that is included below.¹⁶

These incidents clearly demonstrate that insurance plans are skirting their duty to provide contraceptive coverage without cost-sharing as required by the ACA.

COVERAGE DENIALS FOR THE SPECIFIC PRODUCT NEEDED, WITH **NO ACCESSIBLE, TRANSPARENT COST-**SHARING EXCEPTIONS PROCESS

Despite the requirement that plans have a process in place to enable people to get cost-free coverage of the particular method they need, people who contact CoverHer report that this is not happening.

People were denied coverage without cost-sharing for the product they need, were provided little to no information about a cost-sharing exceptions process, or were pushed into processes that do not comply with federal guidance. Where doctors provided certification that the particular product was medically necessary and appropriate, plans overrode those determinations.

- A woman from Louisiana needs NuvaRing for medical reasons. When she picked up her prescription, she was automatically switched to the generic version. When she attempted to access NuvaRing through the exceptions process, she was told by her plan that no such process existed and that NuvaRing would not be covered even if used for a medical reason. As a result, she is forced to pay out-of-pocket \$164 per ring (totaling \$2,132 per year.)
- A 19-year-old in North Dakota switched birth control pills because she was experiencing irregular cycles. Her previous medication was covered without cost-sharing, but after switching to her provider-recommended pill, which alleviated the side effects, she was charged \$40 per pack. When she called her insurance company, United HealthCare, she was not offered an exceptions process but simply pushed to the standard appeals process used for coverage rejections.
- A Texas woman seeking no-cost coverage for the Skyla IUD was told by her marketplace plan that she would have to pay \$900 for that particular IUD. When she asked about the federally required exceptions process, she was told that no process existed.
- A woman from Nevada reported that she used NuvaRing for years with no problem. Her pharmacy dispensed the generic version for three months, and she had

intolerable side effects. She has since learned from CVS Caremark, her insurer's pharmacy benefit manager, that her insurer no longer includes NuvaRing on its formulary. She now has to pay \$180 for a three-month supply. CVS Caremark rejected her doctor's letter explaining why she needs the brand name version. She knows she cannot afford the out-of-pocket costs long-term.

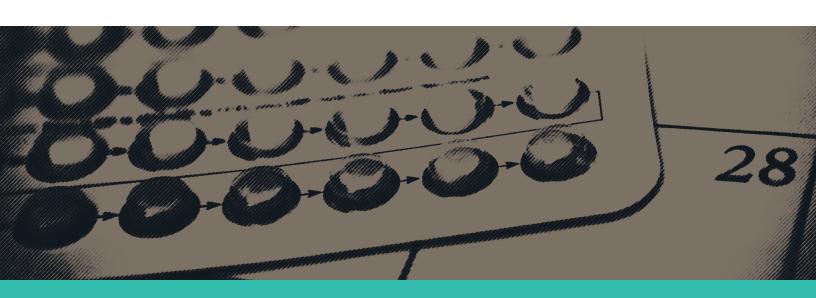
 After her United HealthCare plan through her employer rejected no-cost coverage of a low estrogen birth control pill, a woman was told by the plan that she needed to prove that the pill was "medically necessary" and that her doctor should provide this justification to the insurance company's customer service team. Her doctor provided the information as directed, but the coverage was still denied.

COST-SHARING FOR SERVICES ASSOCIATED WITH BIRTH CONTROL

The law requires coverage without cost sharing of a birth control drug or device, and all the services related to the birth control, such as management of side effects, counseling, and insertion and removal.¹⁷ Despite this requirement, people regularly report illegal cost-sharing for related services:

 One woman has been unable to get a tubal ligation because of the out-of-pocket costs her insurance company has quoted to her for services related to the procedure. When she was told she would have to pay \$3,000 out-of-pocket for a tubal ligation, she asked her insurance company if it was required to cover birth control and was told it did. But she was told that although she would not have to pay for the procedure itself, she would have to pay for "the other parts of the procedure" including anesthesia, which would total \$3,000. A tubal ligation cannot be performed without anesthesia.

- In November 2020, a woman from North Carolina underwent a tubal ligation, and she was told by her insurance company, BlueCross BlueShield of North Carolina, that it would be covered in full. Her plan covered her surgeon and the anesthesiologist, but is applying the costs for the procedure, medications, and facility to her deductible and co-insurance. The total bill is over \$5,700 and the hospital has warned her they will send it to a collections agency.
- One woman from the District of Columbia got an IUD without cost-sharing and returned to her provider for the recommended follow-up appointment, which included an ultrasound. Her BlueCross plan through her employer is requiring her to pay \$300 in cost-sharing for the ultrasound, and the plan rejected her initial appeal of the coverage denial.



THE BIDEN **ADMINISTRATION SHOULD ALSO EDUCATE HEALTH CARE PROVIDERS ABOUT THE BENEFIT**

In some instances, people contact CoverHer because they received preventive care from a provider, but the provider billed the insurance company for the service as diagnostic care or treatment, which incurs cost-sharing. For example, an ultrasound may be necessary when removing an IUD that has moved from where it was placed.¹⁸ This is part of removal and is preventive care, and thus should not result in cost-sharing. Providers and their office staff need education on the scope of the preventive services requirement, including education specifically on billing and coding.

FAILURE TO COVER NEWLY APPROVED BIRTH CONTROL PRODUCTS

The ACA requires coverage of all FDA-approved methods of contraception. Federal guidance specifically requires coverage of 18 methods of contraception "and additional methods identified by the FDA." Over the last four years, the contraceptive marketplace has experienced a burst of innovation, with at least five new contraceptives approved by the FDA in that time.

New technologies offer options for those who cannot use hormonal birth control or who seek lower hormone levels and those who seek different methods of administration and side effect profiles, among other advancements. But insurance companies' coverage of new methods has not kept pace with technological developments, forcing patients to pay out of pocket for newly approved methods.

- A woman in Maryland enrolled in a Federal Employee Health Benefit plan switched to a recently approved progestin-only pill, Slynd, after suffering debilitating headaches on combination pills. After an initial trial offered by her provider, she attempted to fill her prescription and was told it would be \$110 per pack, an out-of-pocket cost she cannot afford. Slynd has no generic equivalent and her insurance company was unable to provide information on how to access coverage without cost-sharing.
- A woman in Oregon was denied no-cost coverage of Phexxi, a recently approved hormone-free vaginal gel, by her insurer, PacificSource. After giving birth to her fourth child, she selected Phexxi to prevent pregnancy during the breastfeeding cessation process because she wanted to avoid hormonal medications. She is forced to pay \$131 per month.

Insurance plans regularly refuse to cover these new contraceptive products without cost-sharing by pointing to the FDA's consumer-facing information about birth control methods, since that is what is referenced in federal agency guidance.¹⁹ The FDA guide is not up-to-date with the latest contraceptive products, so insurance companies have not updated their coverage policies.²⁰ This leaves newly approved methods only truly available to those who can afford to pay out of pocket, eliminating new methods as an option for those without resources.21

THE BIDEN **ADMINISTRATION SHOULD ALSO PREVENT FUTURE BARRIERS TO OVER-THE-COUNTER BIRTH CONTROL**

Federal guidance indicates that it is permissible for an insurance company to require someone to obtain a prescription before it will cover, without cost-sharing, a preventive service that is available over-the-counter (OTC). This includes OTC birth control, like some emergency contraception. Forcing someone to get a prescription for a contraceptive product that is available OTC creates unnecessary hurdles to accessing contraception. These delays are particularly troubling when someone is attempting to access OTC emergency contraception, which is time-sensitive medication. A dozen states have taken action to prohibit insurance companies from requiring a prescription to obtain coverage of some or all OTC birth control.²² The Departments should similarly prohibit health insurance companies from requiring a prescription for coverage of OTC birth control without cost-sharing. Making this a national standard would improve access to OTC birth control now and pave the way for access to new OTC birth control products in the future.²³

While specific to CoverHer callers, the violations of the ACA reported on the hotline demonstrate broader trends in the insurance market. Each event that is reported to CoverHer likely represents many more instances of inappropriate cost-sharing for birth control among other people enrolled in plans issued by the same insurer. Insurance companies' failure to comply with the requirement is restating the very barriers the ACA contraceptive coverage requirement was meant to remedy. The breadth of the problems identified above necessitates systemic solutions to guarantee that the ACA contraceptive coverage requirement reaches its promise for every person enrolled in a plan to which it applies.

Recommendations

The Biden administration must take several actions to ensure that every person whose insurance coverage complies with the ACA contraceptive coverage requirement is able to access that coverage.24

THE DEPARTMENTS OF HEALTH AND **HUMAN SERVICES, LABOR, AND** THE TREASURY SHOULD ISSUE NEW **GUIDANCE THAT:**

- Reiterates the requirement that all **FDA-approved birth control methods** for women must be covered without out-of-pocket costs, including newly approved methods;
- Reiterates that all services associated with contraception, including but not limited to counseling, insertion, removal, and followup for side effects, must be covered without cost-sharing;
- Reiterates the requirement that plans have a cost-sharing exceptions process that enables coverage without cost-sharing of the specific product a person needs, that is "easily accessible, transparent...sufficiently expedient...[and] not unduly burdensome on the individual or a provider," and that defers to the provider's determination;
- Creates a standard, easy-to-use costsharing exceptions form to be used across issuers. Current guidance recommends plans model their cost-sharing exceptions form on the Medicare Part D exceptions form, but plans have not adopted this recommendation over the last five years. A new standard form would build on the Departments' prior recommendation and should be no longer than one to two pages, only ask for necessary information, and include timely deadlines—such as 24 to 48 hours—to ensure people can access their product as quickly as possible;
- Prohibits insurers from requiring a prescription to obtain no-cost coverage of over-the-counter birth control products.

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Recommendations continued

THOSE DEPARTMENTS MUST **DISSEMINATE THE NEW GUIDANCE** TO ALL AGENCIES THAT ENFORCE THE CONTRACEPTIVE COVERAGE **REQUIREMENT AND/OR HANDLE** NONCOMPLIANCE COMPLAINTS. **INCLUDING:**

- state enforcement agencies;
- regional offices of the Department of Labor, which oversees self-funded plans;
- the Office of Personnel Management, which oversees the Federal Employee Health Benefit Program;
- the Center for Consumer Information and Insurance Oversight, Compliance & Enforcement Division/Oversight Group, which oversees non-federal government plans.
- The agencies charged with enforcement must robustly enforce the law, in response to complaints from individuals or documented instances of plan non-compliance.25

- When federal agencies take on the role of reviewing plan documents, they must thoroughly review plan documents to ensure that plans are in compliance with the requirements of the ACA contraceptive coverage requirement.
- The FDA should update its Birth Control Guide to include all contraceptive methods, including methods that have been recently approved and establish a process for regular updates in the future.
- The Departments must conduct a public awareness campaign to ensure that all individuals are aware of the ACA's contraceptive coverage requirement, what they should expect in terms of no-cost coverage, and how to file complaints for non-compliance. The Departments should also work to educate health care providers, so that they properly bill for these preventive services and so that they can be advocates for their patients in getting the coverage they deserve.

ENDNOTES

- The ACA contraceptive coverage requirement reaches cisgender women, transgender men, nonbinary people, and others with a need to prevent pregnancy. This report uses the term "woman" or "women" in circumstances where the data cited is not inclusive of everyone, regardless of gender, who has a need to prevent pregnancy.
- Nat'l Women's L. Ctr. (NWLC), New Data Estimates 64.3 Million Women Have Coverage of Birth Control and Other Preventive Services Without Out-of-Pocket Costs (Nov. 2020), https://bit.
- See, IMS Inst. for Healthcare Informatics, Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013, (2014), available at http://www. plannedparenthoodadvocate.org/2014/IIHI_US_Use_of_Meds_ for_2013.pdf, The Express Scripts Lab, Express Scripts 2015 Drug Trend Report Health Insurance Exchange (March 2016), available at http://lab. express-scripts.com/lab/~/media/ bed6ee9784474511a8534c397e346d56.ashx, and Jonathan M. Bearak et al., Changes in out-of-pocket costs for hormonal IUDs after implementation of the Affordable Care Act: an analysis of insurance benefit inquiries, 93 Contraception 139 (2016) available at http://www.contraceptionjournal.org/article/S0010-7824(15)00575-2/abstract.
- NWLC, Access to Contraceptives During The Covid-19 Pandemic And Recession (July 2020), https://nwlc.org/wp-content/ uploads/2020/08/NWLCIssueBrief_BCandCOVID-19.pdf.
- NWLC, STATE OF BIRTH CONTROL COVERAGE: HEALTH PLAN VIOLATIONS OF THE AFFORDABLE CARE ACT (2015), https://bit. ly/3y938xL, and U.S. Department of Health & Human Services, U.S. Department of Labor, & U.S. Treasury, (May 11, 2015) FAQs on Affordable Care Act Implementation (part 26), retrieved from https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ Downloads/aca_implementation_faqs26.pdf (hereinafter 2015
- NWLC, THE AFFORDABLE CARE ACT'S BIRTH CONTROL BENEFIT: PROGRESS ON IMPLEMENTATION AND CONTINUING CHALLENGES (July 2016), https://nwlc.org/wp-content/uploads/2016/07/The-ACAs-BC-Benefit-Report-1.pdf.
- Health Res. & Servs. Admin., Women's Preventive Services Guidelines, https://www.hrsa.gov/womens-guidelines-2019 (last reviewed Oct. 2020).
- 8
- U.S. Food & Drug Admin., Birth Control Guide, https://www.fda. gov/media/135111/download (last visited Aug. 24, 2021). Notably, since that time, the FDA has updated the chart because one female sterilization method was removed from the U.S. market. Currently, the chart has 17 birth control methods for women.

- 10 Supra note 5, 2015 Guidance.
- 11
- 12 See 26 CFR 54.9815-2713T(a)(4), 29 CFR 2590.715-2713(a)(4), 45 CFR 147.130(a)(4).
- 13 Supra note 5, 2015 Guidance.
- 14 ld.
- 15 Id.
- 16 CoverHer also regularly receives contacts from individuals with Medicaid coverage or grandfathered plans that do not have to comply with the ACA contraceptive coverage requirement. Those are not included in the examples below.
- U.S. Department of Health & Human Services, U.S. Department of Labor, & U.S. Treasury. (Feb. 20, 2013). FAQs on Affordable Care Act Implementation (part XII), retrieved from https:// www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca implementation_faqs12.
- IUD removals requiring ultrasound are an anticipated event. While somewhat rare, they are mentioned as possibly necessary in the information provided to patients and are still part of the preventive service.
- Supra note 9, FDA Birth Control Guide.
- Reporting in the press documented the issue of excluding new methods of birth control. Michelle Andrews, Contraception Is Free to Women, Except When It's Not, NPR (July 21, 2021, 5:06 AM), https://n.pr/2WdBF0Z.
- Even if an insurer disputes whether a newly approved method is a unique contraceptive method category for the purposes of coverage, the cost-sharing exceptions process should enable people to access coverage expediently. As described in the report, that exception process is not functioning as intended by the Departments.
- NWLC, Remove Barriers and Expand Access to Birth Control, 22 https://bit.ly/3gx8ooG (last visited Aug. 24, 2021).
- 23 Multiple companies are working to bring contraceptive methods out from behind the pharmacy counter over the next several
- For recommendations for state policymakers and insurance companies, please see NWLC, Access to Birth Control Without Out-of-Pocket Costs: Improving and Expanding the Affordable Care Act's Contraceptive Coverage Requirement (forthcoming 2021).
- Michelle Andrews, Contraception Is Free To Women, Except When It's Not, NPR (July 21, 2021), https://n.pr/3mREvC4.

