Emergency Contraception & Medicaid: A State-by-State Analysis and Advocate's Toolkit







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Overview The Institute for Reproductive Health Access, the National Health Law Program, the National Latina Institute for Reproductive Health Access and Ibis Reproductive Health are pleased to present to the reproductive health advocacy community: Emergency Contraception & Medicaid: A State-by-State Analysis and Advocate's Toolkit. This toolkit has two purposes. The first is to provide an overview of the range of issues that women on Medicaid currently face in accessing emergency contraception (EC). The second purpose is to identify specific steps that advocates can take at the local level to address barriers that may exist in their state and to lay the groundwork for eventual Medicaid coverage of non-prescription EC. By working together at the state and federal level, we have the potential to greatly increase access to EC for many low-income women.

In June 2004, the American Society for Emergency Contraception, the Compton Foundation, the John Merck Fund and the Open Society Institute co-hosted an Emergency Contraception Funding Strategy Meeting. During the meeting, advocates from across the country discussed the implications of the U.S. Food and Drug Administration's rejection of the petition to permit Plan B® emergency contraception to be sold over-the-counter. The FDA's decision was examined under the lens of the three overarching priorities identified in From Secret To Shelf: How Collaboration is Bringing Emergency Contraception to Women': educating women about emergency contraception; educating clinicians, pharmacists, policymakers and other stakeholders; and, removing barriers to obtaining the pills within 72 hours after unprotected sex. Eleven priorities emerged from the meeting. Yet, one priority was repeatedly mentioned by national and local advocates as central to ensuring that all women, regardless of income, have access to EC: broadening and deepening state-level advocacy on Medicaid reimbursement.

In order to elevate this discussion, a diverse group of advocates, researchers and health care professionals was convened to examine Medicaid reimbursement of EC. The Institute for Reproductive Health Access facilitated the first meeting of the EC & Medicaid Working Group in August 2004. The working group, composed of over 20 local and national reproductive health, policy and advocacy groups, identified two overarching areas that required further research: current coverage of Plan B® within state Medicaid programs and the process to add over-the-counter drugs to state Medicaid drug formularies.

A smaller research subcommittee was formed by staff of the Institute for Reproductive Health Access, Ibis Reproductive Health, the Massachusetts Department of Health, the National Health Law Program and the National Latina Institute for Reproductive Health to address the issue of how women on Medicaid would be affected by the 'dual-label' product being considered for FDA approval, which would maintain the prescription requirement for those under 15 while allowing direct, non-prescription access to women aged 16 and older. Specifically, the subcommittee wanted to explore current Medicaid coverage of non-prescription products, in order to anticipate how a non-prescription or dual-label emergency contraceptive product might be treated by state Medicaid programs. However, rather than reveal the potential obstacles to coverage of non-prescription Plan B®, this research uncovered significant and persistent gaps in coverage of the prescription product. While it is incumbent upon Barr Laboratories, the company that manufactures Plan B®, to ensure that their product is approved for coverage under each state's Medicaid program, advocates must also initiate and strengthen efforts to improve access to EC for women on Medicaid.

As this analysis will demonstrate, universal coverage of prescription EC under state Medicaid programs is within reach. A few states do not cover EC under their Medicaid programs, and in some states, it remains unclear whether Medicaid covers EC. In some states that do cover EC, barriers to access, including complex and unnecessary prior authorization requirements and misinformation about EC provided through client hotlines, persist. Undoubtedly, these barriers significantly impact the ability of a population at high risk for unintended pregnancy to access this important prevention method.

The potential switch from prescription to non-prescription or 'dual-label' status will clearly present new challenges. Many Medicaid programs are not designed to handle 'dual-label' products, or even over-the-counter medications. If women on Medicaid are forced to obtain prescriptions for EC even after it becomes available over-the-counter, as our brief analysis on the topic indicates, they will be effectively excluded from the benefits of a non-prescription product.

Emergency Contraception & Medicaid: A State-by-State Analysis and Advocate's Toolkit provides a general overview of prescription drug coverage under Medicaid, specific barriers to EC access, and a look at Medicaid coverage of EC in the 50 states and the District of Columbia as of September 2005. The last section offers steps advocates can take to ensure universal Medicaid coverage of EC, remove barriers where they exist and begin a dialogue to ensure eventual coverage of non-prescription EC.

Methodology

After quickly learning that significant gaps in Medicaid coverage existed for prescription emergency contraception, the research subcommittee of the EC & Medicaid Working Group sought to update a 2000 report from the Henry J. Kaiser Family Foundation, Medicaid Coverage of Family Planning Services², which lists Medicaid coverage of EC based on responses to a survey disseminated by Kaiser in 1999. Working group researchers informally surveyed state-based advocates, state Medicaid websites, recipient hotlines and state Medicaid personnel to update the 2000 data. In an effort to uncover the ease or difficulty with which a Medicaid recipient could find out about Medicaid coverage of EC, researchers first sought out public sources of information (i.e. websites, hotlines) and then contacted state Medicaid staff directly when this information could not be otherwise located.

Due to limited resources, the first priority for data updates was given to those state Medicaid programs that did not cover EC in 2000, did not respond to the 1999 survey or in which coverage of EC depended on the context of the medical visit. Where possible, attempts were also made to verify that states that covered EC under their Medicaid program in 2000 continue to do so in 2005, and what limits, if any, they place on this coverage. The 2000 and 2005 findings are presented side-by-side in *Table 1: State-by-State Medicaid Coverage of Emergency Contraception*.

Limitations

The EC & Medicaid Working Group and research subcommittee are voluntary collaborations with no dedicated financial resources for meetings, research or publications. The research herein, particularly the update of the 2000 Kaiser Family Foundation data, was conducted informally via personal interviews, web site and literature reviews and anonymous calls to state Medicaid hotlines. No formal survey was conducted to verify the 2005 data. The analysis, therefore, can provide clear direction on some issues related to Medicaid and emergency contraception but cannot be considered definitive without quantitative verification. We urge advocates to use this analysis and toolkit as a starting to point to verify Medicaid coverage and restrictions of EC in their state and to inform the research subcommittee of any errors, changes or improvements to coverage that they uncover.

Prescription Drug Coverage Under Medicaid

State Medicaid programs can include prescription drug coverage as an "optional" Medicaid service. Indicating its importance as part of medically necessary treatment, all 50 states and the District of Columbia include prescription drugs in their Medicaid benefits package. The prescription drug benefit is extensively regulated in the Medicaid law. States must follow general Medicaid principles, in addition to specific prescription drug rules mandated under The Omnibus Budget Reconciliation Acts of 1990 and 1993.³

Family planning services and supplies are mandatory services under Medicaid.⁴ The Medicaid law does not define what specific services and supplies states must provide.⁵ States have the option to include services which prevent or delay pregnancy and/or fertility services. In addition, states have the discretion to determine the specific services and supplies that will be covered as family planning.⁶

General Medicaid Principles that Apply to Prescription Drugs

For both "mandatory" (e.g. family planning) and "optional" (e.g. prescription drugs) services, states must apply general Medicaid rules, all of which support timely, reasonable access to EC:

Amount, Duration and Scope. Each covered service, including prescription drugs, must be in sufficient amount, duration and scope to reasonably achieve its purpose. The state may not arbitrarily deny or reduce the amount, duration or scope of services to an otherwise eligible recipient because of the diagnosis, type of illness, or condition. The state may impose appropriate limits on a service based on medical necessity or utilization control criteria. In the case of EC, this means that a state may not cover only one EC pill, when two pills are required to complete the treatment. A state may possibly impose limits on coverage to EC in circumstances where they deem regular contraceptives more appropriate.

Reasonable Promptness. Federal law requires the provision of Medicaid covered services with "reasonable promptness." This means that services must be provided in a reasonably timely manner.⁸ This rule supports access to EC for women on Medicaid within 72 hours, the time period in which the Plan B® label deems it to be most effective.

Statevideness. The amount, duration and scope of coverage must be the same statewide, unless the state has received permission from the Secretary of the Department of Health and Human Services (HHS) to waive this requirement. Thus, a state Medicaid program cannot choose, for example, to cover EC in one part of the state, but not another.

Comparability. In addition to being low-income, persons eligible for Medicaid also must fit into a "category." That is, a person must be linked to a minor child or be pregnant, a minor, or elderly, or have a disability. The persons in these categories are, in turn, included in one of two groups — "categorically needy" and "medically needy" — depending on income. Services, including prescription drugs, made available to any categorically needy individual must not be less in amount, duration, or scope than those services made available to medically needy individuals. Moreover, services made available to any individuals in a categorically needy or medically needy group must be equal in amount, duration and scope for all individuals within the group. Thus, states may not make EC available to some groups, but not others, in a way that would violate the comparability requirement.

Freedom of Choice. Generally, a Medicaid beneficiary is entitled to a free choice of participating providers. In the case of EC and other contraceptive and family planning services, 'freedom of choice' can only be limited under a demonstration waiver granted by the Secretary of Health and Human Services. Enrollment in a managed care plan, discussed below, cannot restrict this right, unless the managed care program is being operated under this special waiver.¹¹

Notice and Hearing. Individuals who are denied covered benefits are entitled to written notice and an opportunity for a fair hearing to challenge the denial. ¹² As a practical matter, Medicaid beneficiaries who are denied EC at the pharmacy counter might need to pay out-of-pocket and then seek reimbursement from the Medicaid agency as an inappropriate denial of payment for the service.

How States Can Limit Access to Prescription Drugs

Once states meet both the mandatory and optional general requirements that should ensure timely and reasonable access to prescription drugs, they have flexibility in controlling access to and cost of these drugs using a number of mechanisms. States can:

Exclude Certain Drugs. There are several types of drugs that a state does not have to cover (e.g. anorexia, weight loss, or weight gain drugs). Among the drugs that states can exclude are non-prescription or over-the-counter drugs. For those states that provide coverage for over-the-counter drugs, they typically require a prescription from an authorized provider in order to cover it.¹³ Both of these issues have implications for non-prescription EC access for women on Medicaid, and are addressed later in On the Horizon: Over-the-Counter Access.

Impose Co-Payments: States can impose nominal co-payments (e.g. co-payments of \$.50 to \$3.00) for certain services. However, no co-payments may be imposed for emergency or family planning services or on children ages 18 (or at state option, up to age 21) or younger. Also, a provider cannot deny a service due to a patient's inability to pay the co-payment. ¹⁴ Therefore, Medicaid beneficiaries should not be charged a co-payment or denied access to EC due to failure to pay a co-payment.

Require Prior Authorization: States may require prior authorization, which constitutes additional information from the provider on the medical necessity of the drug in addition to the prescription, of any outpatient drug. States with prior authorization must have mechanisms in place to provide responses within 24 hours of a request for prior authorization, and provide for the dispensing of at least a 72-hour supply of a covered outpatient drug in an emergency situation. The implications of prior authorization requirements on access to EC are addressed in Existing Barriers to Access.

Establish Drug Formularies: A drug formulary is a list of medications that identifies drugs that will be covered under a state Medicaid program. States use drug formularies to restrict access to certain types of drugs or classes of drugs, largely to control costs. The guidelines for the establishment of drug formularies are included in Appendix I.

Limit Payments to Pharmacists: States also can limit access by limiting the fees paid to pharmacists – both for the actual purchase of the drug and the dispensing fee. ¹⁶ In addition, states are required to pay "reasonable" dispensing fees to pharmacists. To hold down costs, some states have been reducing both the purchase payment and the dispensing fee.

Impose Other Limitations: States also are permitted to impose limitations, called utilization controls, on the minimum and maximum quantities per prescription or on the number of refills, provided such limitations are necessary to discourage waste.

Managed Care Plans

The federal Balanced Budget Act allows states to enroll Medicaid beneficiaries into managed care plans on a mandatory basis, without having to seek special permission from the federal government through waivers.¹⁷ It is important to understand the types of managed care plans that operate in the state and in which Medicaid beneficiaries are enrolled. Covered outpatient drugs dispensed by Medicaid managed care organizations (MCOs), including Health Maintenance Organizations (HMOs), are not subject to the requirements discussed

above.¹⁸ A state can give HMOs and MCOs wide discretion to set their own policies on, for example, formularies and prior authorization policies. In contrast, primary care case management (PCCM) plans must follow the regular Medicaid rules described throughout this analysis.

Managed care enrollment has resulted in a number of problems associated with prescription drug benefits, especially in the HMO or MCO model of managed care:

Increased Utilization Controls: Beneficiaries in managed care may face more limitations on the number of prescription drugs and the number of refills permitted without prior authorization.

Restrictive Drug Formularies. If definitions of medical necessity are written or are applied too narrowly, the managed care plan may be denying payment for prescription drugs inappropriately. It is important to ensure contract language between managed care plans and the state is sufficient to include coverage of EC, and in all of the circumstances in which it is needed. In some cases, EC and other family planning supplies might be specifically excluded from the health plan's scope of covered benefits. The beneficiary and/or dispensing pharmacist or provider will need to seek payment for the service directly from the state Medicaid agency.

Lack of Information and Referral: Managed care programs participating in Medicaid can refuse to provide, reimburse for, or provide coverage of a counseling or referral service if the organization objects to the provision of the service on moral or religious grounds. ¹⁹ Thus, a plan does not have to provide information on how to access the service outside of the plan network. However, the state maintains a responsibility to provide information to help beneficiaries access these types of services. In practice, beneficiaries often do not get adequate information to access services in a timely fashion.

In New York State, Fidelis, a Catholic-run HMO, excludes family planning drugs, including EC, from its drug formulary. Because Fidelis objects to the provision of certain services, like family planning, on moral or religious grounds, it does not provide information on how to access these services outside of the plan network. While the state maintains a responsibility to provide information on how to access excluded services, it is often difficult for beneficiaries to get this information when and where they need it.

Freedom of Choice: Some HMOs and MCOs require beneficiaries to get their prescriptions filled at pharmacies that have entered into contracts with the managed care plan. These pharmacies may not be convenient for beneficiaries. However, under the special 'freedom of choice' rule for family planning services, EC should be available from any pharmacy or family planning provider that participates in Medicaid. However, how these out-of-plan providers get paid may be an issue.

Prescription drug coverage and payment rules will vary from managed care plan to managed care plan. But, these rules must be consistent with general Medicaid rules that are meant to protect access to services and that continue to apply in the managed care context.

Existing Barriers to EC Access Under Medicaid

Despite advocacy efforts to ensure the wide availability of emergency contraception, many low-income women on Medicaid may not experience timely or comprehensive access to it. In 1999 and 2000, the Kaiser Family Foundation conducted a survey to determine which state Medicaid plans covered EC. The study reported that at least 19 states did not cover prescription-only EC, four states had limited EC coverage depending on the context of the patient visit, and three states did not respond to the survey.

Our follow-up research indicates that of the 26 states that did not cover EC, did not respond to the 1999 survey or limited access based on the context of the visit, 19 states now appear to cover Plan B® under their state Medicaid program (as of September 2005). In the remaining seven states, policies remained unclear, lack of coverage persisted, or managed care settings precluded verification of universal coverage (i.e. EC coverage could not be confirmed for each managed care plan that existed in the state). Further, one state began limiting EC coverage in cases of sexual assault or incest only.

While significant progress has been made to expand Medicaid coverage for EC, universal and easily accessible coverage remains elusive. At least two states, Minnesota and Mississippi, do not cover Plan B® under any circumstances. Fifteen other states limit access to EC through managed care programs, utilization controls, prior authorization requirements or based on the context of the visit. *Table 1: State-by-State Medicaid Coverage of Emergency Contraception* provides an overview of the original Kaiser survey results, the 2005 updates and restrictions on EC access under Medicaid in individual states.

It is not clear why states would elect to not cover Plan B®, particularly since the federal government provides them with a 90% matching rate for family planning services and products. One possibility is that states have not removed Preven, the dedicated EC product that was taken off the market in 2004, from their drug formularies and replaced it with Plan B®. At least two states, Florida and Minnesota, continue to list Preven on their drug formularies.

In states that administer Medicaid managed care programs, such as Arizona, some low-income women may be unaware that their plan is affiliated with a sectarian-sponsored health system and, therefore, excludes family planning services, including EC. While these women may still obtain EC under Medicaid's 'freedom of choice' provision, the process to do so may prove more burdensome than for those Medicaid recipients outside of managed care, or those whose managed care plan provides comprehensive family planning coverage.

Without Medicaid coverage of EC, low-income women who rely on Medicaid as their primary source of coverage for family planning services may find the cost of EC prohibitively expensive. While Title X clinics typically play an important role in EC provision to low-income women by offering it at reduced rates or for free, many women do not know of or cannot geographically access this resource.

Prior Authorization

As detailed in the previous section, *Prescription Drug Coverage under Medicaid*, a significant barrier that affects Medicaid recipients' ability to access EC in select states is the prior authorization requirement. EC is most effective if taken within 72 hours of unprotected sex, but the sooner a woman can access EC, the more effective it is at preventing an unintended pregnancy. While obtaining prior authorization for a patient, the pharmacist or provider must dispense at least a 72-hour supply of a covered outpatient drug in an emergency situation.²⁰ However, the patient may have to pay out-of-pocket for this emergency supply and ask for a hearing following the authorization to ensure reimbursement.

For states with drug formularies, it is important to ensure that Plan B® is included on these lists. Otherwise, women and pharmacists will have to go through the extra step of obtaining prior authorization in order for EC to be covered.

Misinformation

Another potential barrier to EC access for Medicaid beneficiaries is the lack of consistent information about EC on Medicaid hotlines and websites, and from state Medicaid employees. Research uncovered that many employees charged with responding to inquiries about Medicaid benefits are not aware of what EC is or whether their state Medicaid program covers it. For example, numerous Medicaid hotline personnel confused EC with RU-486, the FDA-approved medical abortion pill, and stated that EC is not covered because Medicaid does not cover abortifacients.²¹ Other Medicaid personnel were unable to provide a clear answer on whether EC is in fact covered by their state's program.

Many state-administered Medicaid websites containing information about covered products and services were similarly misleading and difficult to navigate. For example, some websites continue to list Preven on their drug formularies, even though Preven is no longer on the market. Preven is also listed on web-accessible formularies in states that actually cover Plan B®, which may create confusion for Medicaid recipients and providers. It was also difficult to determine whether EC is covered through simple searches on the Medicaid websites.

'Pharmacy Access' and Medicaid Coverage

Seven states – Alaska, California, Hawaii, Maine, New Hampshire, New Mexico and Washington – currently allow women to access emergency contraception directly through pharmacists, without first having to visit a provider for a prescription. (Massachusetts' pharmacy access law will go into effect in 2006.) In many 'pharmacy access' states, pharmacists are directly reimbursed by Medicaid. However, some state Medicaid programs do not provide reimbursement for the time spent counseling patients. By limiting reimbursement to the cost of the actual medication, Medicaid is creating a disincentive for pharmacists to provide counseling. Moreover, some pharmacy access states require prior authorization for EC, which unduly burdens low-income women, and defeats the purpose of direct, unfettered access to EC via pharmacies.

Table 1: State-by-State Medicaid Coverage of Emergency Contraception

St. 11	200022	2005	Restrictions
State	200022	2005	
Alabama	-	•	Prior authorization
Alaska	•	•	
Arizona	•	МС	Prior authorization
Arkansas	-	•	
California	•	•	Utilization controls
Colorado	-	•	
Connecticut	-	МС	
Delaware	•	•	
District of Columbia	•	•	
Florida	-		Preven on drug formulary
Georgia	•	•	
Hawaii	•	•	
Idaho	-	•	Prior authorization
Illinois	-	•	
Indiana	•		Exclusion waiver pending ²³
Iowa	-	•	
Kansas	-	•	
Kentucky	Ø	•	Prior authorization
Louisiana	-	•	1 nor authorization
		•	
Maine	<u>-</u>		Daire and animation
Maryland	Ø	•	Prior authorization
Massachusetts	•	•	
Michigan	•	•	
Minnesota	-	-	Preven on drug formulary ²⁴
Mississippi		-	
Missouri	•	•	
Montana	-		No drug formulary
Nebraska	•	•	
Nevada	•	•	Prior authorization
New Hampshire	-	•	
New Jersey	•	•	
New Mexico		•	
New York	•	•	
North Carolina	•	•	Prior authorization
North Dakota	•	•	
Ohio	-	•	
Oklahoma		•	
Oregon	•	•	
Pennsylvania	•	Ø	Coverage only in cases of rape
1 Chrisyivama	-	V	and incest
Rhode Island	•	•	and meest
South Carolina	•	•	
South Dakota		•	
	-		
Tennessee	-	•	
Texas	-	•	
Utah	Ø	•	
Vermont	•	•	
Virginia	•	•	
Washington	•	•	
West Virginia	-		Not on drug formulary
Wisconsin	Ø	•	
Wyoming		МС	

Notes

Covered by Medicaid

Ø Coverage depends on context of visit --- Did not respond to 2000 Kaiser Survey

⁻ Not covered by Medicaid

[☐] Coverage remains unclear MC Coverage depends on managed care plan enrollment

On the Horizon: Over-the-Counter Access

The Federal Food and Drug Administration is currently considering an application that would make Plan B® available over-the-counter to women ages 16 and over while still requiring a prescription for those under 16. This switch will have significant implications for Medicaid recipients as state Medicaid plans are not required to cover over-the-counter drugs, although most do cover a number of over-the-counter family planning supplies. Further, there is no precedent within Medicaid to deal with a 'dual-label' product. Currently, when over-the-counter family planning supplies are covered, most states require a prescription for reimbursement. As has been well-documented in this analysis, requiring a prescription in order for Medicaid beneficiaries 16 or over to access a 'dual-label' EC product effectively impedes them from enjoying the benefit of non-prescription status.²⁵

An Action Plan for Advocates

Action 1: Determine the Status of Medicaid Coverage of EC in Your State

As an advocate, you can have a significant impact on the ability of low-income women on Medicaid to access EC in your state. Using Table 1 as a starting point, determine whether your state Medicaid program covers Plan B®. If not, find out why it's not covered and the process for adding a prescription drug to the formulary. Researching these issues can be conducted through a variety of methods. Most Medicaid programs have a website that contains information on covered services and benefits, as well as phone numbers for hotlines and Medicaid personnel. You can also investigate the status of EC in your state by requesting meetings with officials at your state health department and pharmacy association. We also recommend that you call your Medicaid hotlines to find out what information they are providing to Medicaid recipients who inquire about coverage for EC.

Action 2: If Plan B® is Covered, Determine the Access Barriers

If your state Medicaid program covers EC, your work is not finished. You should try to identify what other barriers, if any, recipients face when attempting to access EC, such as prior authorization requirements or utilization controls. If beneficiaries are automatically enrolled into a managed care plan, they may not realize that their plan excludes EC, or that they are still able to access the medication under the 'freedom of choice' provision. You should also survey local family planning clinics and other providers to find out whether they are being reimbursed for EC in a timely manner. Finally, you should find out whether Medicaid websites and hotlines are providing accurate information about coverage of Plan B® and EC in general.

Action 3: Document and Report Barrier Issues

If you experience or learn about barriers to accessing EC in your state, be sure to document them. Some of these incidents and institutional barriers may amount to violations of federal Medicaid rules. For example, in a state with a prior authorization requirement for EC, the failure to dispense an emergency 72 hour supply of the drug may violate the "reasonable promptness" rule and other prior authorization requirements. Other barriers, such as listing Preven in the drug formulary on a state Medicaid website, may simply reflect a technical oversight that can be easily rectified by educating and/or working with state Medicaid offices. You should contact your local legal service providers or national organizations specializing in Medicaid law, such as the National Health Law Program, to determine the best course of action for remedying any access issue. Details on how to contact the authors of this toolkit and national Medicaid legal organizations are included below and in Appendixes IV and V.

Action 4: Educate Medicaid Personnel

In many states, Medicaid personnel were unable to answer basic questions about EC and coverage of Plan B®. There is a clear need for public education efforts to increase knowledge about EC among Medicaid officials. There are a number of ways to increase

awareness among personnel, such as conducting trainings on EC for Medicaid staff, especially for hotline representatives and those interacting directly with Medicaid recipients; encouraging Medicaid offices to publicize information about EC on their websites, hotlines and in other materials; and, demanding that Medicaid programs update their formularies to reflect coverage of Plan B® and remove any reference to Preven.

Action 5: Educate Medicaid Recipients

It is also essential that Medicaid recipients have information about EC and whether it is covered by Medicaid. Recipients should feel empowered to ask for EC knowing that cost will be not a prohibitive barrier. Advocates can play an important role in increasing access to EC for women on Medicaid by disseminating materials and resources in Medicaid offices, clinics and provider offices with information about EC, Medicaid coverage and how to obtain it.

Checklist: Do Medicaid Barriers to EC Access Exist in My State?			
☐ How easy is it to find out whether Medicaid covers Plan B® in your state?			
□ Do you have a Medicaid drug formulary in your state?			
☐ Is Plan B® listed on the formulary?			
☐ If Plan B® is not listed on the formulary, what is the process for getting it on the			
formulary?			
☐ Is Preven listed?			
☐ How easy is it to obtain Plan B® if you are on Medicaid?			
☐ Are individuals being charged co-pays?			
□ Does a Medicaid recipient need to obtain prior authorization for coverage of			
Plan B®?			
☐ If so, are recipients receiving an emergency supply and a response within 24			
hours?			
☐ Do Medicaid personnel and websites provide accurate information about EC			
and coverage?			
☐ Are there other utilization controls in place, such as a limit on the number of			
refills?			
☐ Are individuals being forced to pay for EC out-of-pocket?			
☐ Are there other barriers facing Medicaid recipients accessing EC?			
☐ Are clinics and providers being reimbursed in a timely manner?			
□ Does your state enroll Medicaid beneficiaries into managed care plans on a			
mandatory basis?			
☐ Is EC excluded from the managed care plan's scope of covered benefits?			
☐ If you are in a 'pharmacy access' state, you might want to ask these additional questions.			
□ What is the process for Medicaid reimbursement when obtaining EC from a			
pharmacy?			
☐ Do pharmacists get reimbursed for time spent counseling patients?			

Do you have an update about EC Medicaid coverage in your state? Do you want help navigating your state's Medicaid program to ensure EC coverage? Contact the Institute for Reproductive Health Access at (415) 285-1377 to report changes to coverage or seek assistance with your efforts.

Appendix I Drug Formularies

Under the Medicaid program, states may use drug formularies with the following restrictions:

- 1. The formulary includes the covered outpatient drugs of any manufacturer who has entered into and complies with a Medicaid rebate program;
- 2. The state's Medicaid plan permits coverage of a drug excluded from the formulary pursuant to a prior authorization program that complies with the requirements discussed above;
- 3. The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the state's Governor or the state's drug use review board;
- 4. A covered outpatient drug is excluded from the formulary with respect to a specific disease or condition for an identified population only if, based on the drug's labeling, the excluded drug does not have significant, clinically meaningful therapeutic advantage (in terms of safety, effectiveness, or clinical outcome) over other drugs included in the formulary, and there is a written explanation (available to the public) of the basis for the exclusion;
- 5. The formulary meets other requirements imposed by the Secretary of Health and Human Services. ²⁶

Appendix II Medicaid Waivers

States have the option to seek "waivers" of certain Medicaid provisions. There are two waiver provisions that are relevant to this discussion. One is the 'freedom of choice' waiver²⁷ and the other is the "section 1115 demonstration project" waiver.²⁸ Under a 'freedom of choice' waiver, for example, the Centers for Medicare and Medicaid Services (CMS) may permit waiver of statewideness, comparability, and 'freedom of choice' to create a primary care case management system which restricts the provider from whom an individual can obtain medical services (except emergency services). However, 'freedom of choice' for family planning services and supplies cannot be waived under this type of waiver. Under a "section 1115 demonstration project" waiver, CMS can permit a state to waive certain important Medicaid protections, such as amount, duration and scope, statewideness, 'freedom of choice' (including for family planning services) and other provisions.²⁹ However, neither of these waiver authorities is unlimited. For example, notice and hearing rights cannot be waived, because these are constitutional rights. Reasonable promptness arguably cannot be waived to the extent that the state seeks to waive the part of the provision which requires that all persons who are eligible be provided with Medicaid with reasonable promptness. This provision embodies the entitlement nature of the Medicaid program. In addition, only those provisions that are necessary to carry out the specific waiver projects can be waived and only for the duration that is necessary. The waiver projects also must carry out the purposes of the Medicaid program. There are further specific limitations on CMS' authority to waive Medicaid provisions.³⁰

Appendix III Medicaid's Drug Rebate Program

Under federal Medicaid rules, drug manufacturers must sign a rebate agreement with the Centers for Medicare and Medicaid Services (CMS) in order for their drugs to be eligible for coverage by Medicaid. Under this agreement, drug manufacturers must pay quarterly

rebates to state Medicaid programs for each of the manufacturer's pharmaceutical products. The program essentially requires pharmaceutical companies to give discounts to Medicaid programs as a condition of receiving Medicaid payments. In order to receive the rebates, states prepare and submit quarterly utilization invoices to each manufacturer and to CMS, indicating the drug and the number of units for which the state paid. Except for the limitations described in Appendix I (e.g. drugs that can be excluded), states must cover all FDA-approved prescription drugs of manufacturers that have entered into a drug rebate agreement for medically accepted indications.³¹

States also may seek supplemental rebates directly from manufacturers, as long as these agreements result in equal or greater rebates than the federal rebate agreement.³² In order to encourage drug companies to enter into supplemental agreements, a state may establish a preferred drug list and subject drugs not on the list to prior authorization procedures.³³ If the state requires prior authorization for "non-preferred" drugs, it must provide a response to a request for prior authorization within 24 hours and also provide coverage for an emergency 72-hour supply while awaiting prior authorization.³⁴

Appendix IV Resources

Center on Budget Policy and Priorities w

www.cbpp.org

The Center on Budget and Policy Priorities is one of the nation's premier policy organizations working at the federal and state levels on fiscal policy and public programs that affect low- and moderate-income families and individuals.

Centers for Medicare and Medicaid Services www

www.cms.hhs.gov

The Centers for Medicare and Medicaid Services (CMS) administers the Medicare program and works in partnership with the states to administer Medicaid, the State Children's Health Insurance Program (SCHIP) and health insurance portability standards.

Kaiser Family Foundation

http://www.kff.org/medicaid/rxdrugs.cfm

The Kaiser Commission on Medicaid and the Uninsured is the main source for the Foundation's work related to the Medicaid and SCHIP programs. Begun in 1991, the Commission is the largest operating program of the Henry J. Kaiser Family Foundation and has brought increased analysis and attention to health coverage issues facing the low-income population for over a decade. Through its reports and briefings, the Commission continues to provide up-to-date information on Medicaid and SCHIP and assesses options for reform.

Medicaid Matters 2005 Campaign

www.medicaidmatters2005.org

This web site was developed through a joint effort by a number of groups, including Community Catalyst, Georgetown University Health Policy Institute, Northwest Federation of Community Organizations, the Center on Budget and Policy Priorities, Neighborhood Health Plan, and Families USA. It has been developed as a resource for people working across the country to protect Medicaid, the health insurance that 50 million of us rely on.

National Health Law Program

www.healthlaw.org

It is critical to focus on preserving health care coverage for those most in need and with fewest resources. NHeLP seeks to provide a seat at the table for representatives of low-income people, to protect consumers in the emerging managed care systems, and to find creative financing solutions that also preserve government's responsibility as provider of last resort.

Appendix IV Contributors



427 Broadway, 3rd Floor, New York, NY 10013

212-343-0114

The **Institute for Reproductive Health Access** (formerly the NARAL Pro-Choice New York Foundation) develops and implements programs that are significantly expanding the availability of abortion and family planning services nationwide, while removing health care obstacles women face today. <u>institute.prochoiceny.org</u>



NATIONAL HEALTH LAW PROGRAM 2639 South La Cienega Boulevard, Los Angeles, CA 90034 310-204-6010

The *National Health Law* Program is a national public interest law firm that seeks to improve health care for America's working and unemployed poor, minorities, the elderly and people with disabilities. NHeLP serves legal services programs, community-based organizations, the private bar, providers and individuals who work to preserve a health care safety net for the millions of uninsured or underinsured. www.healthlaw.org



50 Broad Street, Suite 1825, New York, NY 10004 212-422-2553

The *National Latina Institute for Reproductive Health* works to ensure the fundamental human right to reproductive health care for Latinas, their families and their communities through education, policy advocacy, and community mobilization. www.latinainstitute.org



2 Brattle Square, 4th Floor, Cambridge, MA 02138

617-349-0040

Ibis Reproductive Health aims to improve women's reproductive autonomy, choice and health worldwide. www.ibisreproductivehealth.org

Endnotes

¹ Barbara Pillsbury, Francine Coeytaux and Andrea Johnston, From Secret to Shelf: How Collaboration is Bringing Emergency Contraception to Women (Los Angeles, CA: Pacific Institute for Women's Health, 1999).

- ² The Henry J. Kaiser Family Foundation, *Medicaid Coverage of Family Planning Services* (Washington, DC: The Henry J. Kaiser Family Foundation, 2000), Table II-3, p. 17. Data current as of January 2000.
- ³ These rules are generally codified at 42 U.S.C. § 1396r-8.
- 4 42 U.S.C. § 1296d(a)(4)(C); 42 C.F.R. § 441.20. See 42 C.F.R. § 441.250 et seq.
- ⁵ The federal regulations also do not define the cope of family planning services. See 42 C.F.R. § 440.40(c)
- 6 Health Care Financing Administration, Pub. No. 45-4, State Medicaid Manual § 4270 (transmittal No. 36, September 1988).
- 7 42 C.F.R. § 440.230(b)-(d).
- 8 42 U.S.C. § 1396a(a)(8); 42 C.F.R. § 435.930.
- 9 42 U.S.C. § 1396a(a)(1); 42 C.F.R. § 431.50.
- ¹⁰ 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. § 440.240(a), (b); There are some limits to comparability, such as provision of services in greater amount, duration and scope for pregnant women. 42 C.F.R. § 440.250.
- 11 42 U.S.C. § 1396a(a)(23). Only a § 1115 waiver can restrict freedom of choice for family planning services. 42 U.S.C. § 1315.
- ¹² U.S. Const. Amend. XIV, § I; 42 U.S.C. § 1396a(a)(3); 42 C.F.R. §§ 431.200, 431.206(c), 431.200-431.250; Goldberg v. Kelly, 397 U.S. 254, 266 (1970).
- 13 42 U.S.C. § 1396r-8(k)(4) (Over-the-counter drugs provided with prescriptions are regarded as "covered outpatient drugs").
- ¹⁴ 42 U.S.C. § 1396o(a)(2); 42 C.F.R. § 447.50 et seq.
- ¹⁵ 42 U.S.C. § 1396r-8(d)(1)(A), (5).
- ¹⁶ 42 C.F.R §§ 447.331-447.334 (pertaining to the federal upper limits for which federal Medicaid matching dollars are available); 52 Fed. Reg. 28648 (July 31, 1987).
- 17 42 U.S.C. § 1396u-2.
- ¹⁸ 42 U.S.C. § 1396r-8(j)(1). This provision exempts HMOs and Medicaid managed care plans from the requirements of 42 U.S.C. § 1396r-8, with respect to, for example, rebates, prior authorization requirements, etc...
- ¹⁹ 42 U.S.C. § 1396u-2(b)(3)(B).
- ²⁰ 42 U.S.C. § 1396r-8(d)(1)(A), (5).
- ²¹ This also is incorrect. Medicaid programs are required to at least cover abortion services in cases of rape, incest, and to save the life of the mother under the Hyde Amendment which is attached to annual appropriations bills.
- ²² According to 2000 Kaiser Family Foundation Report, see *supra* note 2.
- ²³ Waiver pending which would exclude coverage of "a drug or device intended to terminate pregnancy after fertilization."
- ²⁴ Minnesota Medicaid officials confirmed that the state did not cover Plan B®. However, Preven is listed on the state's drug formulary.
- ²⁵ While this toolkit addresses only prescription EC, further study must be undertaken to determine the process by which individual state Medicaid programs will deal with a non-prescription or dual-label emergency contraceptive product. In the interim, state advocates are encouraged to begin a dialogue about over-the-counter coverage with state Medicaid employees.
- ²⁶ 42 U.S.C. § 1396r-8(d)(4).
- ²⁷ 42 U.S.C. § 1396n(b).
- ²⁸ 42 U.S.C. § 1315.
- ²⁹ Id. Only provisions in 42 U.S.C. § 1396a can be waived. Not provisions in other sections of Medicaid. There are limits on what and how provisions in 1396a can be waived. See, supra note 12.
- ³⁰ 42 U.S.C. §§ 1396n(b) & 1315.
- 31 42 U.S.C. § 1396r-8(a)-(c). The rebate requirements do not apply to certain single source or innovator multiple source drugs. Supra note 27 at § 1396r-8(a)(3).
- ³² 42 U.S.C. §§ 1396r-8(a)(1), 1396r-8(a)(4), 1396r-8(b)(1)(B).
- ³³ 42 U.S.C. § 1396r-8(d)(1).
- ³⁴ 42 U.S.C. § 1396r-8(d)(5).