North Carolina
State Health Plan
FOR TEACHERS AND STATE EMPLOYEES

Pharmacy Formulary Exclusions Exception Process

Board of Trustees

August 5, 2016

2017 Custom, Closed Formulary

- The Board approved the move to a custom, closed formulary, or drug list, effective January 1, 2017.
- This means that drugs that are excluded from the formulary will not be covered by the State Health Plan.
  - This is applicable to the Traditional Pharmacy Benefit, which includes the CDHP 85/15, the Enhanced 80/20 Plan and the Traditional 70/30 Plan.
- A formulary exclusion exception (exception) process will be available to support Plan members who, per their provider, have a medical necessity to remain on an excluded drug.
- The exception process will be administered by CVS/caremark, the Plan's new Pharmacy Benefit Manager.

Formulary Exception Coverage Criteria

- The exception coverage criteria process will determine if the excluded medication is approved or denied. Approval for coverage criteria may be different for each of the targeted therapeutic classes depending on the number of formulary alternatives that are available in that class.
- The Plan is currently working with CVS to finalize the criteria and process outlined on the following slides.

Formulary Exception Coverage Criteria (DRAFT)

- Below are **example scenarios** for how the process *may* work and cases where it would be approved if there are one or more than one formulary alternatives that are available in a therapeutic class. **Only a provider can make an exception request.**
  - If a provider feels changing the course of medication could negatively impact a member's health and therefore the exception is medically necessary.
  - If the prescriber provides evidence of trial and failure of 3 formulary alternatives (generics and/or formulary brands) in a class where 3 or more alternatives are available, the request will be approved.
  - If the prescriber provides evidence of trial and failure of 2 formulary alternatives (generics and/or formulary brands) in a class where 2 alternatives are available, the request will be approved.
  - If the prescriber provides evidence of trial and failure of 1 formulary alternative (generic and/or formulary brands) in a class where only 1 alternative exists, the request will be approved.
  - In addition to trying or failing formulary alternatives, approval for an excluded drug can also exist if the prescriber provides evidence of an adverse drug reaction or drug contraindication to the formulary alternatives.

The criteria has not yet been finalized.

Formulary Exclusion Exception Process (DRAFT)

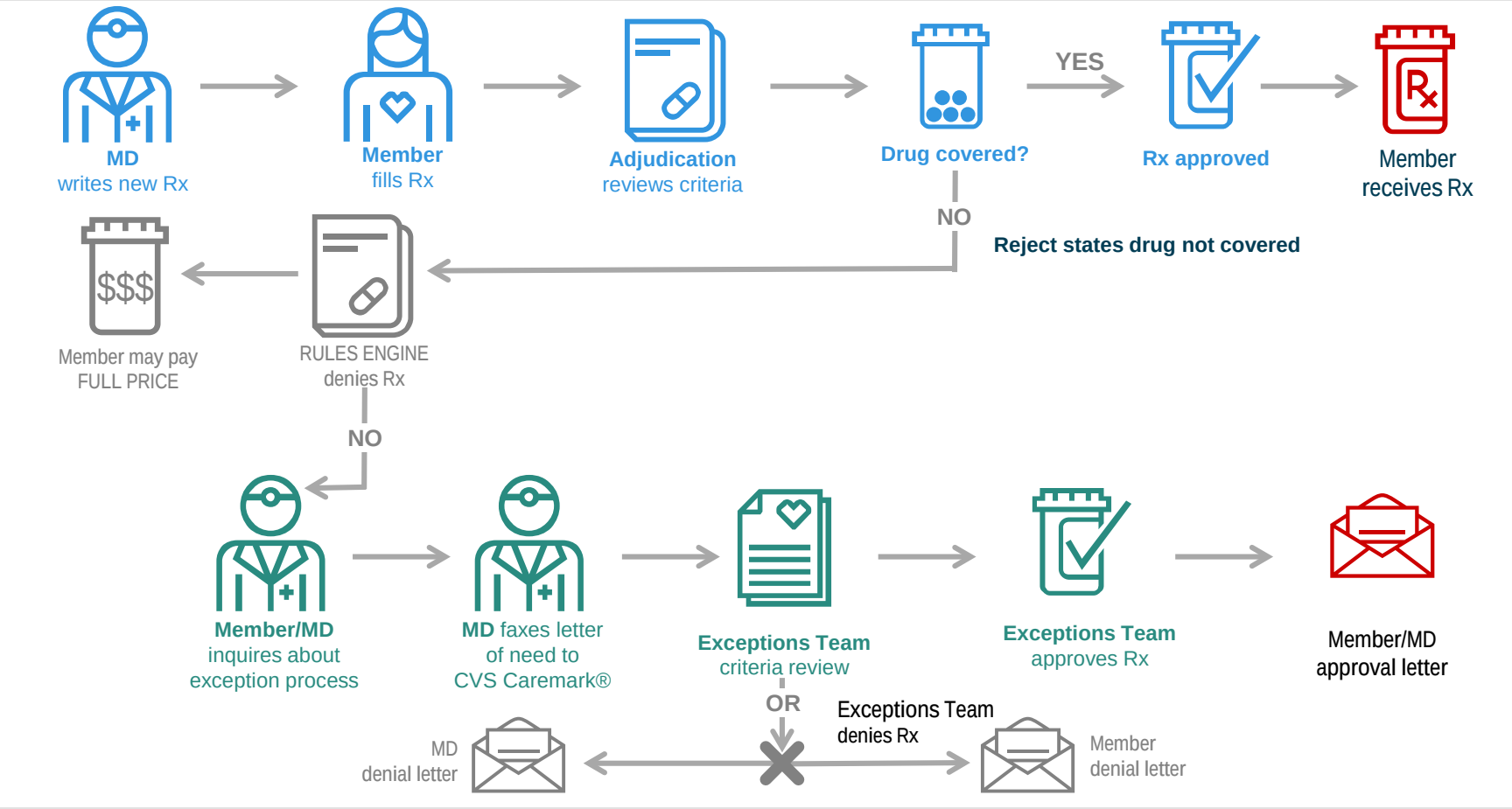
- **The steps below outline the process for requesting an exception for a Plan member:**
  - To request an exception form a member's provider can contact CVS/caremark Customer Care at 888-321-3124; or find the exceptions form online at the Plan's website at www.shpnc.org by clicking Pharmacy Benefits under Plans for Active Employees.
  - Submit exception form to CVS/caremark via fax at 888-487-9257. A letter of medical necessity from the provider should accompany the exception request form.
  - The exceptions team consists of clinicians who review the exception request and medical necessity letter and any relevant information.
  - After the clinical review, the decision (approval or denial) is then communicated to the provider and the member by mail.
  - If the exception request is approved, the exceptions department will enter the necessary override(s). Authorization duration is defined in the specific medication policy.
  - If the exception request is denied based on clinical review, a denial letter is sent to the provider and the member. The denial letter includes directions on how to appeal the denial.

The process has not yet been finalized.

Formulary Exclusion Exception Process Timeline

- **Exceptions are processed within the following time frames from the time that information is received:**
  - Urgent requests from the member's provider are completed typically within 24 hours. Urgent requests should also be noted as such on the exception request form.
  - Urgent is defined "urgent as defined by law (that is, a member's health is in serious jeopardy or, in the opinion of the provider, the member will experience pain that cannot be adequately controlled) while you wait to receive approval of your exception."
  - Non-urgent requests are completed typically within 72 hours.

Exceptions Process – Drug Not Covered



Appendix

1. Formulary Exclusion Exception Process
2. Member/Provider Notice of Approval
3. Member/Provider Notice of Denial

Formulary Exclusion Exception Process

The State Health Plan (Plan) has a custom, closed formulary, or drug list, which includes drugs that are excluded from the formulary and are not covered by the Plan. This is applicable to the Traditional Pharmacy Benefit (which includes the Consumer-Directed Health Plan, the Enhanced 80/20 Plan and the Traditional 70/30 Plan).

A formulary exclusion exception (exception) process is available to support Plan members who, per their provider, have a medical necessity to remain on an excluded drug. The exception process is administered by CVS/caremark, the Plan's Pharmacy Benefit Manager.

There may be circumstances in which the formulary alternatives may not be appropriate for some members. In this case, a member may be approved for the excluded drug with an exception process. An exception is defined as a situation where the member has tried and failed (that is, had an inadequate treatment response or intolerance) to the required number of formulary alternatives; or the member has a documented clinical reason such as an adverse drug reaction or drug contraindication that prevents them from trying the formulary alternatives.

Exceptions Coverage Criteria

The exception coverage criteria process will determine if the excluded medication is approved or denied. Approval for coverage criteria may be different for each of the targeted therapeutic classes depending on the number of formulary alternatives that are available in that class. The below lists **example scenarios** on how the process may work and cases where it would be approved if there are one or more than one formulary alternatives that are available in a therapeutic class.

- If a provider feels changing the course of medication could negatively impact a member's health and therefore the exception is medically necessary.
- If the prescriber provides evidence of trial and failure of 3 formulary alternatives (generics and/or formulary brands) in a class where 3 or more alternatives are available, the request will be approved.
- If the prescriber provides evidence of trial and failure of 2 formulary alternatives (generics and/or formulary brands) in a class where 2 alternatives are available, the request will be approved.
- If the prescriber provides evidence of trial and failure of 1 formulary alternative (generic and/or formulary brands) in a class where only 1 alternative exists, the request will be approved.

In addition to trying or failing formulary alternatives, approval for an excluded drug can also exist if the prescriber provides evidence of an adverse drug reaction or drug contraindication to the formulary alternatives.

In summary, the requested drug will be covered with prior authorization when the following criteria are met:

- Member is using the requested drug for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines).

AND

- The prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Micromedex, current accepted guidelines).

AND

- The member has tried and experienced an inadequate treatment response or is intolerant to the required number of formulary alternatives.

OR

- The physician (or member) has a documented clinical reason for their patient experiencing any adverse drug reaction or drug contraindication to the formulary alternatives.

Follow the steps below in requesting an exception for a Plan member:

1. To request an exception form a member's provider can contact CVS/caremark Customer Care at 888-321-3124; or find the exceptions form online at the Plan's website at www.shpnc.org by clicking Pharmacy Benefits under Plans for Active Employees.
2. Submit exception form to CVS/caremark via fax at 888-487-9257. A letter of medical necessity from the provider should accompany the exception request form.
3. The exceptions team consists of clinicians who review the exception request and medical necessity letter and any relevant information.
4. After the clinical review, the decision (approval or denial) is then communicated to the provider and the member by mail.
5. If the exception request is approved, the exceptions department will enter the necessary override(s). Authorization duration is defined in the specific medication policy.
6. If the exception request is denied based on clinical review, a denial letter is sent to the provider and the member. The denial letter includes directions on how to appeal the denial.

Exceptions are processed within the following time frames from the time that information is received:

- Urgent requests from the member's provider are completed typically within 24 hours. Urgent requests should also be noted as such on the exception request form.
- Urgent is defined "urgent as defined by law (that is, your health is in serious jeopardy or, in the opinion of your provider, you will experience pain that cannot be adequately controlled) while you wait to receive approval of your exception."
- Non-urgent requests are completed typically within 72 hours.

Notice of Approval

Date:

To:

Plan Member Name:
Plan Member ID:

Prescriber Name:
Prescriber Phone:
Prescriber Fax:

Dear:

CVS/caremark, the State Health Plan's Pharmacy Benefit Manager, has received a Formulary Exclusion Exception from your provider for coverage of {{APPROVEDDRUG}}.

As long as you remain covered by the State Health Plan and there are no changes to your plan benefits, this request is approved for the following time period:

{{APPROVESTART}} – {{APPROVETHRU}}

Approvals may be subject to dosing limits in accordance with FDA approved labeling, accepted compendia, evidence based practice guidelines or your prescription drug plan benefits.

If you have not already done so, you may ask your pharmacist to fill the prescription.

If you have questions, please call Customer Care at 888-321-3124.

Sincerely,

CVS/caremark

cc: Dr. {{PHYFIRST}} {{PHYLAST}}

PA# {{DISPLAY_PAGNAME}} {{PANUMBER}} {{USER}}

Notice of Denial

Date:

To:

Plan Member Name:
Plan Member ID:

Prescriber Name:
Prescriber Phone:
Prescriber Fax:

Dear:

CVS/caremark, the State Health Plan's Pharmacy Benefit Manager, has received a Formulary Exclusion Exception from your provider for {{APPROVEDDRUG}}. Your request for an exception was denied because it did not meet the established criteria defined by your prescription plan. The reason(s) for denial was:

{{DENIALREASON}} <<DENIALNOTES>>

This decision relates specifically to the amount you will pay for this medicine under your prescription benefit drug plan. You may request a free copy of the criteria or guidelines used in making the decision and any other information related to the determination by calling 800-294-5979.

If you disagree with this decision, you may appeal it. If you choose to submit an appeal, it must be received within 180 days of the date of this letter. You or your authorized representative (who may be your provider) may submit an appeal of this denial in writing along with any documentation that will support your appeal. That documentation should include any information that you or your provider believe supports your claim. This information could include a letter from your provider describing why the requested medication is necessary, clinical notes, test results, or any other supporting documentation. If you choose to appeal this decision, please mail or fax your appeal to:

{{APPEAL_FIRST_NAME}} <<APPEAL_LAST_NAME>>
{{APPEAL_ADDRESS1}} <<APPEAL_ADDRESS2>>
{{APPEAL_CITY}}, {{APPEAL_STATE}} {{APPEAL_ZIP}} Fax: {{APPEAL_FAX}}

If you or your provider believe your situation is urgent as defined by law (that is, your health is in serious jeopardy or, in the opinion of your provider, you will experience pain that cannot be adequately controlled while you wait for a decision on your appeal), you or your authorized representative (who may be your provider) may request an expedited appeal by calling Customer Care at 888-321-3124 or by faxing your appeal to {{APPEAL_FAX}}.

Your appeal will be reviewed within 30 days after it is received. Urgent appeals are reviewed within 72 hours after being received. You will receive a letter explaining the decision. Important information about your rights to appeal is provided on the next page.

If your appeal is denied and you do not agree with the decision, and if your prescription benefit coverage is subject to the new claims and appeals requirements imposed by the Patient Protection and Affordable Care Act of 2010 (PPACA), you may have the right to request an external review of the decision as permitted by the terms of the PPACA. If your group plan is subject to the Employee Retirement Income Security Act of 1974 (ERISA), you may also have the right to bring a civil action under ERISA Section 502(a). Please refer to your benefit plan materials for more information. Important information about your rights to appeal is provided on the next page.

If you have questions, please call Customer Service at 888-321-3124.

Sincerely,

Prescription Appeals Department
CVS/caremark

cc: Dr. {{PHYFIRST}} {{PHYLAST}}

PA# {{DISPLAY_PAGNAME}} {{PANUMBER}} {{USER}}
Claim Amount (if available):
Service Date (if applicable): {{TODAY}}

If CVS Caremark was provided with diagnosis or treatment codes for your claim for {{APPROVEDDRUG}}, that information is provided here: ICD-9 diagnosis code: {{ICD9}}
Associated diagnosis: {{DIAGNOSIS}} CPT treatment code: <<CPT_CODES>>
Associated treatment: <<CPT_DESCRIPTION>>
You may wish to contact your health care provider for further information.

Important Information about Your Rights to Appeal

What if I need help understanding this denial? Please call Customer Care at the number on your benefit ID card or in your benefit plan materials if you need assistance understanding this notice or our decision to deny you a service or coverage.

What if I don't agree with this decision? You have a right to appeal any decision not to provide you or pay for an item or service (in whole or in part).

How do I file an appeal? If you choose to submit an appeal for coverage, it must be received within 180 days of the date of this letter. You or your authorized representative (who may be your provider) may submit an appeal of this denial in writing along with any documentation that will support your appeal. That documentation should include any information that you or your provider believe supports your claim. This information could include a letter from your provider describing why the requested medication is necessary, clinical notes, test results or any other supporting documentation. Please mail or fax your appeal to:

{{APPEAL_FIRST_NAME}} <<APPEAL_LAST_NAME>>
{{APPEAL_ADDRESS1}} <<APPEAL_ADDRESS2>>
{{APPEAL_CITY}}, {{APPEAL_STATE}} {{APPEAL_ZIP}} Fax: {{APPEAL_FAX}}

What if my situation is urgent? If your situation meets the definition of urgent under the law, your review will be conducted on an expedited basis after we receive your appeal. Generally, an urgent situation is defined by law as one in which your health is in serious jeopardy or, in the opinion of your provider, you will experience pain that cannot be adequately controlled while you wait for a decision on your appeal. If you or your provider believe your situation is urgent as defined by law, you or your provider may request an expedited appeal by calling Customer Care at 888-321-3124 or by faxing your appeal to {{APPEAL_FAX}}. Urgent requests must be clearly identified as "urgent" when submitted. In certain situations, you may also be able to request a simultaneous external review of your claim.

Who may file an appeal? You or someone you name to act for you (your authorized representative) may file an appeal. You may name your provider, a relative, friend, advocate or anyone else as your appointed representative. When submitting your appeal, please provide a letter appointing that person as your representative or provide other similar proof giving that person legal permission to act on your behalf. This letter must be submitted with your appeal.

Can I provide additional information about my claim? Yes, you may supply any additional information when you submit your claim. You may also wish to present testimony on your behalf.

Can I request copies of information relevant to my claim? Yes, you may request copies (free of charge) by calling Customer Care at 888-321-3124.

What happens next? If you appeal, we will review our decision and provide you with a written determination. If we continue to deny the payment, coverage or service requested or you do not receive a timely decision, and if your prescription benefit coverage is subject to the new claims and appeals requirements imposed by the PPACA, you may be able to request an external review of your claim by an independent third party, who will review the denial and issue a final decision. You may also have the right to file a civil action under ERISA if your group health plan is subject to ERISA. Please refer to your benefit plan materials if you need assistance understanding your rights.

Here is a listing of State Consumer Assistance Programs:

The U.S. Department of Labor's Employee Benefits Security Administration (EBSA) may also be a helpful resource to participants and beneficiaries in need of assistance. EBSA may be contacted at: 866-444-EBSA (3272) or www.askebsa.dol.gov.

STATE	CONTACT INFORMATION
Alabama	No program
Alaska	No program
America n	No program
Arizona	No program
Arkansas	
Arkansas	Arkansas Insurance Department Consumer Services Division 1200 West Third St Little Rock, AR
California	California Department of Managed Care and Department of Insurance California Help Center 980 9th St, Suite #500 Sacramento, CA 95814 (888) 466-2219
Colorado	No program
Connecticut	Connecticut Office of the Healthcare Advocate 153 Market St, 6th Floor Hartford, CT 06103 (866) 466-4446 http://www.ct.gov/oha

STATE	CONTACT INFORMATION
Delaware	No program
District of Columbia	District of Columbia Healthcare Finance Office of the Ombudsman 899 North Capitol St, NE, Room 6037 Washington, DC 20002 (877) 685-6391 healthcareombudsman@dc.gov http://ombudsman.dc.gov
Florida	No program
Georgia	Georgia Office of Insurance and Safety Fire Commissioner Consumer Services Division 2 Martin Luther King, Jr. Drive West Tower, Suite 716 Atlanta, GA 30334 (800) 656-2298 http://www.oci.ga.gov/consumerservice/home/aspx
Guam	No program
Hawaii	No program
Idaho	No program
Illinois	Illinois Department of Insurance 100 Randolph St, 9th Floor Chicago, IL 60601 (877) 527-9431 http://www.insurance.illinois.gov
Indiana	No program
Iowa	No program
Kansas	Kansas Insurance Department Consumer Assistance Division 420 SW 9th Street Topeka, KS 66612 (800) 432-2484 (785) 296-7829 http://www.ksinsurance.org CAP@ksinsurance.org
Kentucky	No protram
Louisiana	No program
Maine	Maine Consumer Assistance Program Consumers for Affordable Healthcare 12 Church St Augusta, ME 04338 (800) 965-7476 http://www.mainecahc.org consumerhealth@mainecahc.org

STATE	CONTACT INFORMATION
Maryland	Maryland Office of the Attorney General Health Education and Advocacy Unit 200 St. Paul Place, 16th Floor Baltimore, MD 21202 (877) 261-8807 http://www.oag.state.md.us/Consumer.HEAU.htm heau@oag.state.md.us
Massachusetts	Massachusetts Consumer Assistance Program 30 Winter Street, 10th Floor Boston, MA 02108 (800) 272-4232 www.massconsumerassistance.org
Michigan	Michigan Department of Insurance and Financial Services HICAP 611 W. Ottawa Street Lansing, MI 48933 (877) 999-6442 http://www.michigan.gov/HICAP
Minnesota	No program
Mississippi	Health Help Mississippi 800 North President Street Jackson, MS 39202 1-877-314-3843 www.healthhelpms.org healthhelpms@mhap.org
Missouri	Missouri Department of Insurance 301 W. High St, Room 830 Jefferson City, MO 65101 (800) 726-7390 http://www.insurance.mo.gov consumeraffairs@insurance.mo.gov
Montana	No program
Nebraska	No program
Nevada	Nevada Governor's Office for Consumer Health Assistance 555 East Washington Ave, #4800 Las Vegas, NV 89101 (702) 486-3587 (888) 333-1597 http://www.govcha.state.nv.us cha@govcha.state.nv.us
New Hampshire	No program
New Jersey	No program

STATE	CONTACT INFORMATION
New Mexico	New Mexico Consumer Assistance Program 1120 Paseo De Peralta, Room 428 Santa Fe, NM 87504 1-855-427-5674 (1-855-4 ASK OSI) http://www.OSI.state.nm.us mchb.grievance@state.nm.us
New York	Community Service Society Community Health Advocates 105 East 22nd Street New York, NY 10010 (888) 614-5400 cha@cssny.org http://www.communityhealthadvocates.org Language line is available for non-English speakers
North Carolina	Health Insurance Smart NC NC Department of Insurance 430 N. Salisbury Street Suite 1018 Raleigh, NC 27603 Toll free: 877-885-0231 http://ncdoi.com/Smart/
North Dakota	No program
Northern Mariana Islands	No program
Ohio	No program
Oklahoma	Oklahoma Insurance Department Five Corporate Plaza 3625 NW 56th, STE 100 Oklahoma City, OK 73112 Toll-Free: (800) 522-0071 (in-state only) Phone: (405) 521-2991 Email: ombudsman@oid.ok.gov http://www.ok.gov/oid/Consumers/Consumer_
Oregon	Oregon Insurance Division Oregon Health Connect 1435 NE 81st Avenue, Suite 500 Portland, Oregon 97213-6759 (855) 999-3210 http://www.oregonhealthconnect.org healthconnect@211info.org

STATE	CONTACT INFORMATION
Pennsylvania	Pennsylvania Consumer Assistance Program Pennsylvania Insurance Department Bureau of Consumer Services 1209 Strawberry Square Harrisburg, PA 17111 (877) 881-6388 http://www.pahealthoptions.com
uerto Rico	No program
Rhode Island	Rhode Island Consumer Assistance Program Rhode Island Parent Information Network 1210 Pontiac Avenue Cranston, RI 02920 (855) 747-3224 http://www.RIREACH.org
South Carolina	No program
South Dakota	No program
Tennessee	No program
Texas	No program
Utah	No program
Vermont	Vermont Consumer Assistance Program Vermont Legal Aid 264 North Winooski Ave Burlington, VT 05402 (800) 917-7787 www.vtlegalaid.org
Virginia	No program
Virgin Islands	US Virgin Islands Division of Banking and Insurance 1131 King Street, Suite 101 Christiansted St. Croix, VI 00820 (320) 773-6459 http://lgt.gov.vi
Washington	No program
West Virginia	No program
Wisconsin	No program
Wyoming	No program