For Health or Profit?

How HMOs Restrict Access to Single-Source Prescription Drugs Critical to the Health of New Yorkers

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We welcome feedback on our reports. Please contact Alex Camarda, Policy Director, at 718-822 2049 to provide your thoughts on this report or discuss collaboration on implementing its initiatives.

Dear Reader:

Among the many important issues facing New Yorkers today, perhaps none is more fundamental than adequate and affordable health care. This encompasses access to vital prescription drugs that are essential for treating chronic conditions. Unfortunately, decisions about the best prescription drug choices for our families are being taken away from doctors and patients by insurance companies that too often place profits above the health of their members.

At the heart of this concern are single-source drugs. Single-source drugs are unique in their formulation, dosage, and delivery—they have no generic equivalent because of current patent laws and are often times more expensive. The prices cause HMOs to create policies and formularies that steer the insured toward prescription drugs that will increase their profit margins, rather than those that the doctor and patient decide are the best course of treatment. Insurance companies block access to single-source drugs through high co-payments and company-approval requirements that pass the burden onto the patient.

The following is an investigative report showing how HMOs in New York State restrict the use of single-source drugs and which are the worst offenders. The report concludes with potential solutions to this problem that will ensure that medical decisions lie in the hands of our doctors and not HMOs.

Regards,

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SECTION 1:
RESTRICTIONS TO ACCESSING SINGLE-SOURCE DRUGS

Single-Source (Brand Name) Drugs vs. Generic Drugs

- In general, a single-source drug contains a unique active ingredient (responsible for the drug's effect), dosage, and dosage form, all of which are approved by the Food and Drug Administration (FDA) as safe and effective to treat a particular illness. Single-source drugs are under patent protection. The patent guarantees that no other pharmaceutical company may manufacture the drug until the patent expires.

- The FDA requires generic medication to contain the same active ingredient as well as the same amount of active ingredient as the brand name. Generic drugs must also be equal in safety, strength, route of administration, quality, and directions. Any manufacturer who meets these FDA requirements can market his/her generic medication and compete with the brand name drug once the patent expires.

Single-Source (Brand Name) Drugs vs. Generic Drugs Continued

- According to the FDA, generic drugs have the same effect on the body as brand name drugs do. The major difference is price.

- In 2007, the average brand name drug was 3 times the price of the average generic drug ($119.51 vs. $34.34).[1]

- Manufacturers of brand name drugs argue they must price their medications higher than generics to cover costs associated with research and development - expenses generic manufacturers do not incur.

A Conflict of Interest?

- If the best medication for a patient has a generic equivalent, the latter should clearly be prescribed in order to save costs for the entire health care system. However, if a single-source drug still has patent protection, generic prescriptions are not an option.

- The problem arises with drugs that treat specific conditions (such as high cholesterol). While some of these drugs have less expensive generic equivalents, others are only available as the more expensive brand name drug. Health insurance companies (HMOs) want to control costs while physicians want to treat their patients with the most effective and safe medications, whether they be brand name or generic.

A Conflict of Interest? (Cont.)

- Central to the argument of this presentation is what is referred to as **heterogeneity of response**. This phenomenon is well-documented and basically means that medicine is very individualized, so that depending on the type of medication to treat a particular illness no two patients will respond the same. In some cases, even medications of the same type will affect patients differently.

- HMOs, however, restrict access to many single-source drugs through what are called "cost-containment strategies." These are meant to encourage or even force physicians to prescribe drugs that, in their professional opinion, are not the safest or most effective drugs for a particular patient. Depending on the illness and the patient, certain single-source drugs may be the only effective treatment available; yet they cannot be prescribed because of HMO restrictions.

Cost Containment Strategies

- **Formularies** are lists issued by HMOs that indicate the prescription drugs they cover as well as the associated patient co-payments.

- **Tier-based formularies** are the most common. They work by placing medications on different tiers, where the co-payments rise with every following tier. For example:

TIER 1 -- $10 co-payment (generic brand)
TIER 2 -- $25 co-payment (preferred brand)
TIER 3 -- $45 co-payment (non-preferred brand)

- Tier-based formularies are intended to encourage generic use and compliance with the HMO's formulary through increasing patient out-of-pocket costs for using non-preferred brand-name drugs. In other words, high co-payments are intended to discourage the use of non-preferred single-source drugs.

Cost Containment Strategies (Cont.)

- **Prior Authorization (PA):** requires approval by the insurance company before a drug will be covered. PA is intended to limit the use of certain drugs to only those patients who meet specific medical requirements.
- **Quantity Limitation (QL):** limits the amount of medication or number of prescriptions that can be purchased at one time. QLs are intended to ensure physicians and patients are following specific medication guidelines.
- **Step Therapy (ST):** requires a patient to try older or less expensive medication before a newer brand name will be covered. ST is intended to decrease costs by enforcing the use of less expensive medication with similar evidence of safety and efficacy as compared to medication with a newer brand name.
- **Exclusion (E):** excludes certain medication from the formulary, which is therefore is not covered.

Off-Label Drug Use

- **Off-label drug use** is the consumption of medication in a manner different from the approved indication of the FDA. Physicians use their individual expertise and available evidence when deciding to prescribe a medication for off-label use.

- Many single-source drugs have off-label use, and there are often not enough available guidelines and evidence to determine how safe and effective off-label use will be. The physician's knowledge and level of expertise is, therefore, very important in this type of prescribing.

- HMOs vary in the restrictions they place on off-label drug use. In some cases, despite the physicians' expertise, they will not cover the medication for certain off-label uses.

- Appeal processes are available, but they can be time consuming and there is no guarantee the HMO will cover the medication.

SECTION 2:
INVESTIGATORY METHODS

Investigatory Methods

- In order to determine the degree to which HMOs in New York State (NYS) restrict access to single-source drugs, we:

  1. Identified the HMOs offering prescription drug benefits through the NYS department of Health.

  2. Analyzed their three-tier formularies to determine the coverage restrictions across several classes of medications.

HMOs Surveyed

The following NYS HMOs were investigated to determine their restrictions on single-source medications:

Aetna Health, Inc.
Capital District Physicians' Health Plan, Inc.
CIGNA HealthCare of New York, Inc.
Connecticare of New York, Inc.
Empire HealthChoice HMO, Inc. d/b/a Empire BlueCross BlueShield HMO
Excellus Health Plan, Inc.
GHI HMO Select, Inc.
Health Insurance Plan of Greater NY, Inc.**
Health Net of New York, Inc.
HealthNow New York, Inc.
Independent Health Association, Inc.
MVP Health Plan, Inc

*For the purposes of this report, we used HMOs having more than 100,000 enrollees of employee and private plans in New York (excluding governmental programs) according to the NYS Department of Insurance

** Critical information related to restrictions on prescriptions drugs on the formulary for the Health Insurance Plan of Greater NY, Inc. (HIP) was not readily available and, therefore, HIP was not included in the survey. However, they do utilize a formulary and engage in the same practices as other companies spotlighted that restrict access to brand-name drugs.

Medication Classes Investigated

- The following medication classes were investigated to determine restrictions placed on single-source drugs:

  1. Cardiovascular
  2. Cancer
  3. Autoimmune Specialty
  4. HIV/AIDs
  5. Chronic Pain/Addiction

- The most commonly prescribed single-source medications were determined for each drug category based on the ExpressScripts 2007 Drug Trend Report.[2]

- For drug classes where this information was not included in the report, single-source drugs were selected that had unique active ingredients and/or dosage forms.

SECTION 3:
FINDINGS & IMPLICATIONS

Cardiovascular Medications

- **Cardiovascular disease (CVD)** is the leading cause of death in NYS and accounted for 43% of all deaths (67,700) in 2002. [3]
- High cholesterol and hypertension (high blood pressure) are major risk factors for heart attack, stroke, heart failure, and peripheral artery disease.
- Heterogeneity of response has been documented for many medications in this class. For example, a recent 2008 review article found that, while ACEIs and ARBs were equally effective in treating hypertension, ACEIs lead to a significantly higher incidence of coughing, a serious side effect for both these medication classes. What is noteworthy is that many ACEIs are available as generics in the United States, whereas ARBs are not.[4]

Cardiovascular Medications (Cont.)

Brand Name (Generic Name)	Drug Class	Common Indications
Lipitor (Atorvastatin)	HMG-CoA Reductase Inhibitor	High Cholesterol
Vytorin (Simvastatin and Ezetemeibie)	Antilipemic Combination	High Cholesterol
Crestor (Rosuvastatin)	HMG-CoA Reductase Inhibitor	High Cholesterol
Diovan (Valsartan)	ARB	Hypertension; HF
Cozaar (Losartan)	ARB	Hypertension; HF

Cardiovascular Drug Restrictions

	Lipitor	Vytorin	Crestor	Diovan	Cozaar
Aetna	$$;ST;QL	ST;QL	ST;QL	QL	QL
CDPHP		$$		$$	
Cigna			$$;PA;ST	PA;ST	PA;ST
Connecticare	$$;ST;QL	$$;QL;ST	ST;QL	$$	$$
Empire	QL	$$;QL;ST	$$;QL	QL	QL
Excellus	$$;QL;ST	$$;ST	QL;ST	QL	$$;QL;ST
GHI	$$;ST		$$;ST		
Health Net	$$;PA;QL	PA;QL		PA	$$;PA
Health Now	QL	QL	QL	QL	$$;QL
Independent		$$		ST	$$;ST
MVP				PA;QL	$$;ST;PA

$$ - highest co-payment
ST - step therapy required
QL - quantity provided at one time is limited
PA - prior authorization required

Cancer Medications

- Many of these drugs are very expensive. For example, when first introduced, Gleevec® costs ranged from $29,000 to $57,500 per patient per year. Many of these medications are either the only or most effective treatments for certain cancers.[5]
- Many of these medications are used off-label and HMOs differ on what uses they will and will not approve, often requiring a prior authorization process.

Brand Name (Generic Name)	Drug Class	Common Indications
Lupron Depot (Leuprolide)	GnRH Analogue	Prostate Cancer
Xeloda (Capecitabine)	Anti-metabolite	Colorectal and Breast Cancer
Gleevec (Imatinib Mesylate)	Kinase Inhibitor	Leukemias
Temodar (Temozolomide)	Alkylating Agent	Giloblastoma Multiforme (Brain Tumor)
Tarceva (Erlotinib)	Kinase Inhibitor	Lung and Pancreatic Cancer

GnRH - gonadotropin-releasing hormone

Cancer Medication Restrictions

	Lupron	Xeloda	Gleevec	Temodar	Tarceva
Aetna		QL	QL	QL	QL
CDPHP					
Cigna	PA		PA		PA
Connecticare		PA	PA	PA	PA;QL
Empire	$$;PA	PA	PA		PA
Excellus			QL		PA;QL
GHI	*	*	*	*	*
Health Net	*		PA		
Health Now			PA	PA	PA
Independent			PA		
MVP			PA;QL		

$$ - highest co-payment
ST - step therapy required

QL - quantity provided at one time is limited
PA - prior authorization required

* - no information available

Autoimmune Specialty Drugs

- **Rheumatoid arthritis (RA)** is a chronic disease characterized by inflammation of the joints. It can lead to long-term joint damage, resulting in chronic pain, loss of function, and disability. RA continues indefinitely, with great patient variability in flares, severity of symptoms, and response to treatments (high heterogeneity of response).

- **Autoimmune specialty medications** represent breakthroughs in treating patients with these debilitating conditions that are traditionally difficult to treat.

- These medications are very expensive ($15-$20,000 per patient per year), injectable biologic medications. Currently, there exists no approval process to obtain generic biological medications in the United States.

Autoimmune Specialty Drugs (Cont.)

- Like cancer medications, these medications are often used off-label, and HMOs differ on the what uses they will and will not approve, often requiring a prior authorization process.

Brand Name (Generic name)	Drug Class	Common Indications
Enbrel (Etanercept)	DMARD	Moderate to Severe Rheumatoid Arthritis
Humira (Adalimumab)	DMARD	Moderate to Severe Rheumatoid Arthritis
Raptiva (Efalizumab)	Antipsoriatic	Moderate to Severe Psoriasis

DMARD - disease modifying anti-rheumatic drugs

Autoimmune Specialty Drug Restrictions

	Enbrel	Humira	Raptiva
Aetna			$$
CDPHP	PA	PA	PA
Cigna	PA	PA	*
Connecticare	$$;PA;QL	$$;PA;QL	$$;PA;QL
Empire	$$;PA;QL	$$;PA;QL	$$;PA
Excellus	$$;PA;QL	$$;PA;QL	$$;PA;QL
GHI	QL	QL	*
Health Net	*	*	*
Health Now	QL;PA	QL;PA	QL;PA
Independent	PA	PA	PA
MVP	QL;PA	$$;PA;QL	*

$$ - highest co-payment
ST - step therapy required

QL - quantity provided at one time is limited
PA - prior authorization required

* - no information available

HIV/AIDS Medications

- According to a report on HIV/AIDS drug adherence published by the Committee on Oversight and Government Reform, "research shows that if patients are not highly adherent, the medicines stop working and the virus becomes resistant. As a consequence, it may become difficult to treat either the patient or any others to whom the virus might be transmitted with existing drugs. For both individual patients and the epidemic overall, therefore, it is extremely important to promote effective adherence, continuity of care, and follow-up for patients." [6]
- "Adherence" in this context can be considered "taking medication regularly." Any restrictions on HIV/AIDs medications placed by HMOs could, therefore, potentially lead to non-adherence.

HIV/AIDS Medications (Cont.)

Brand Name (Generic Name)	Drug Class	Common Indications
Truvada (Tenofivir and Emtricitabine)	nRTI and NRTI	HIV-1 In Combination With Other Antiretroviral Agents
Atripla (Tenofivir, Emtricitabine, Efavirenz)	nRTI, NRTI, NNRTI	HIV-1 In Combination With Other Agents or as Monotherapy
Selzentry (Maraviroc)	Entry Inhibitor	HIV-1 Resistant to Multiple Agents
Isentress (Raltegravir)	Integrase Inhibitor	HIV-1 Resistant to Multiple Agents
Fuzeon (Enfuvirtide)	Entry Inhibitor	HIV-1 Resistant to Multiple Agents

nRTI - nucleotide reverse transcriptase inhibitor
NRTI - nucleoside reverse transcriptase inhibitor
NNRTI - non-nucleoside reverse transcriptase inhibitor

HIV/AIDS Medication Restrictions

	Truvada	Atripla	Selzentry	Isentress	Fuzeon
Aetna		$$	$$	$$	$$
CDPHP					ST
Cigna		$$			*
Connecticare	$$	$$	$$		$$;PA
Empire	*	*	*	*	*
Excellus		QL			$$
GHI	*	*	*	*	
Health Net		QL	$$	*	
Health Now		*	PA		
Independent					PA
MVP					

$$ - highest co-payment
ST - step therapy required

QL - quantity provided at one time is limited
PA - prior authorization required

* - no information available

Chronic Pain/Addiction Medications

- Acute pain, after surgery or trauma, comes on suddenly and lasts for a limited time. Chronic pain persists - for months, years, or even life.
- Opiate (narcotic) analgesics are for many patients the only effective chronic pain medications. It is well documented that patients have different responses to different narcotic medications (high heterogeneity of response). Therefore, pain medication must be individualized based on diagnosis, personality, intellect, age, and previous treatment outcomes.
- Suboxone is one of only two medications approved by the FDA for outpatient treatment of opiate dependence.

Chronic Pain/Addiction Medications (Cont.)

Brand Name (Generic Name)	Drug Class	Common Indications
Suboxone (Buprenorphine and Naloxone)	Opiate Partial Agonist and Opiate Antagonist	Opioid Dependence
Fentora (Fentanyl Buccal Tablet)	Narcotic Analgesic	Breakthrough Pain in Patients With Cancer
Opana (Oxymorphone Hydrochloride)	Narcotic Analgesic	Moderate to Severe Chronic Pain
Oxycontin (Oxycodone Controlled Release)	Narcotic Analgesic	Moderate to Severe Chronic Pain

Chronic Pain/Addiction Med Restrictions

	Suboxone	Fentora	Opana	Oxycontin
Aetna	$$	$$;PA;QL	$$	QL
CDPHP	PA	E	E	$$
Cigna	$$	$$;PA	$$	QL
Connecticare	$$	$$;PA		QL
Empire	*	$$;PA;QL	$$	QL
Excellus		$$;PA;QL	$$	$$;QL;ST
GHI	*	*	*	*
Health Net	*	$$;PA;QL	$$	$$; PA; QL
Health Now		*	*	
Independent	PA	*	$$;PA	
MVP	$$;PA;QL	$$;PA;QL	$$;PA;QL	$$;PA;QL

$$ - highest co-payment
ST - step therapy required
QL - quantity provided at one time is limited
PA - prior authorization required
* - no information available
E - drug excluded & not covered

Restrictions by HMOs

HMO	Drugs Restricted/ Total Drugs Investigated*	% of Drugs Restricted of Total Investigated	# of Investigated Drugs With No Information Available
Empire	15/16	94%	6
Connecticare	19/22	86%	0
Aetna	18/22	82%	0
Excellus	15/22	68%	0
Cigna	13/20	65%	2
Health Now	12/19	63%	3
Health Net	10/16	63%	6
Independent	10/20	50%	2
GHI	4/8	50%	14
CDPHP	10/22	45%	0
MVP	9/21	43%	1

*- figure for total drugs investigated differs as some HMOs do not have relevant information available for all drugs. If no information was available, the drug was not included in total drugs investigated.

Restrictions by Drug

	Drug	Disease/ Therapeutic Area	Total Restrictions	# of Companies Restricting	Percentage of Companies Restricting
1	Fentora	Chronic Pain/Addiction	20	8/8	100%
2	Raptiva	Autoimmune	13	7/7	100%
3	Diovan	Cardiovascular	12	10/11	91%
4	Humira	Autoimmune	18	9/10	90%
5	Enbrel	Autoimmune	17	9/10	90%
6	Gleevec	Cancer	10	9/10	90%
7	Opana	Chronic Pain/Addiction	11	8/9	89%
8	Cozaar	Cardiovascular	17	9/11	82%
9	Oxycontin	Chronic Pain/Addiction	14	8/10	80%
10	Suboxone	Chronic Pain/Addiction	8	6/8	75%
	Vytorin	Cardiovascular	15	8/11	73%
	Lipitor	Cardiovascular	16	7/11	64%
	Crestor	Cardiovascular	14	7/11	64%
	Atripla	HIV/AIDS	5	5/8	63%
	Tarceva	Cancer	8	6/10	60%
	Fuzeon	HIV/AIDS	6	5/9	56%
	Selzentry	HIV/AIDS	4	4/9	44%
	Xeloda	Cancer	3	3/10	30%
	Temodar	Cancer	3	3/10	30%
	Lupron	Cancer	3	2/9	22%
	Isentress	HIV/AIDS	1	1/8	13%
	Truvada	HIV/AIDS	1	1/9	11%

Concerns with High Co-Payments (Tier 3)

- There is a growing body of literature that suggests raising out-of-pocket costs through the use of a 3-tier formulary results in increased use of inpatient and emergency medical services for patients with chronic diseases.[7] This finding suggest that patients may try to avoid high co-payments by not taking their prescribed medication, which in turn makes them more ill.

- One study analyzing the link between rising co-payments and prescription drug use found that adherence among the lowest income populations (< $30k/year) for medications used to treat diabetes and heart failure significantly decreased when co-payments were increased by only 10%.[8]

- Of particular concern are the traditionally poorer African-American and Hispanic American populations, which display higher rates of chronic diseases such as cardiovascular disease, diabetes, mental health, and HIV/AIDS. [9]

Concerns with Other Types of Restrictions

- Prior authorization and step therapy are very time-consuming and burdensome, for both physicians and pharmacists. In both cases, the time it takes for healthcare professionals to fill out forms is valuable time taken away from patients.

- As discussed, many single source drugs are used off-label. This use often requires prior authorization or step therapy, and there is no guarantee an HMO will approve the use of the medication, which takes the process of decision-making out of physicians' hands.

- In the worst-case scenario, a physician may decide against prescribing a medication that requires prior authorization or step therapy as the paperwork and time needed to complete the process are too burdensome. Physicians have years of training; it is disturbing that their prescribing may be dictated by HMO restrictions rather than their medical expertise.

Specialty Biologic Drugs

- As this report has shown, specialty biologic drugs are subject to multiple restrictions (see slide 23).
- These medications are used for patients that are often the sickest and most debilitated, with diseases such as severe rheumatoid arthritis, psoriasis, and cancer.
- There is currently no FDA approval process for generic biologic drugs. Therefore, it is very unlikely that manufacturers will lower the price of these medications as they face no competition even when their patent expires.
- Legislation is underway to create a generic approval process, but the timetable for its passage is uncertain.[10]
- Due to the extremely high costs and lack of generic equivalents for specialty medications, HMO restrictions will continue to be a major barrier to physicians in prescribing these important drugs.

SECTION 4:
Solutions

Solutions- S2938

- **Empowering Physicians**

• When an insurer has changed the drug medication of a member insured by a group health policy issued to a generic alternative which the member's prescribing physician attests is not the equivalent of the original prescribed drug, the insurer shall continue to cover and pay for the original drug.

- **Controlling Expensive Co-Payments**

- The co-payment and co-insurance amount with respect to any covered drug shall not exceed the cost of the drug to the health plan.

- Should a health plan include an out of pocket limit on non-pharmacy benefits it shall also provide that out of pocket expenses for covered prescription drugs shall be included as medical benefit expenses under the plan's general out of pocket expense cap.

- Should an insurer provide for tiered co-payment and co-insurance amounts, it shall also provide that the maximum co-payment and co-insurance amount shall not exceed five times the lowest co-payment and co-insurance amount.

Solutions- S2938

- **Limiting Insurers' Restrictions on Access to Prescription Drugs**

• If less expensive drugs are required to be taken by the patient initially, more expensive single-source medication must be made available following compliance with step therapy and a determination by the patient's physician that the drug remains medically necessary.

• Insurers must submit their prescription drug formularies to the New York State Insurance Department (NYSID) on an annual basis and whenever they are altered.

• NYSID shall issue guidelines for insurers to follow in making determinations of medical necessity with respect to prescription drug coverage. Health insurers provide their drug formularies to the State Insurance Department on an annual basis and when drugs are removed from the formulary, except in instances where removal is the result of the availability of a generic equivalent.

•A patient receiving coverage for a drug on an insurer's existing formulary shall not be denied coverage upon a change in the formulary if his or her physician determines that drug to be medically necessary.

Other Proposals for Consideration

- Some physicians should be allowed to bypass the PA and ST restrictions based on specific training and expertise. For example, an oncologist should not have to adhere to PA, ST, or QL when prescribing a cancer drug. This would also solve problems associated with getting approval for off-label use. (Independent Health, Inc was the only HMO investigated that had such a policy.)

- Certain single-source drugs should not be placed at the highest co-payment tier if improper adherence to the drug is a threat to the community (e.g. HIV/AIDS medications).

- The FDA should be encouraged to approve a process for generic biologic medications.

Report Limitations

- Many of the formularies we accessed did not include information about their coverage of some of the study drugs. Therefore, it is unclear what kind of restrictions these HMOs place on these medications.

- Only major HMOs defined as having more than 100,000 enrollees were used in this study. Therefore, we do not know the extent to which smaller HMOs restrict single-source drugs.

- We only used HMOs in NYS. As such, our findings can say little about the national picture of single-source drug restrictions.

Report Limitations (Cont.)

- The practice of medicine is ever changing as new studies emerge. Some of these studies demonstrate that certain single-source drugs are not as safe and/or effective as was previously thought. For example, the recent ENHANCE trial has shown that Vytorin® is no more effective at reducing plaque artery build up as the generic medication Simvastatin; Simvastatin is one of two active ingredients in Vytorin®. Therefore, it may be unfair to HMOs to criticize them for placing harsh restrictions on drugs such as this when strong evidence is available that raises serious doubt about the supposed benefits of the higher-cost single-source drugs.[11]

Conclusions

- Prescription drug spending is currently about ten percent of national health expenditures. As such, HMOs have to try to control the costs of prescription drugs, not just for the sake of their own profits, but also to keep premiums affordable to all NYS citizens enrolled in their plans.

- Therefore, it may not be reasonable or fair to force HMOs to remove their restrictions on expensive single-source drugs. The challenge is to determine which restrictions are beneficial to both patients and the health care system, and to what degree they represent the HMOs' interests.

Closing Statement

- We created this report to advocate for the use of all available prescription drugs to best serve the health of NYS patients enrolled in these HMOs. While we understand that restrictions on single-source medications are sometimes necessary, this report finds that too often, HMOs are using these restrictions in ways that run counter to the health and well-being of the NYS population they serve.

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