



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans

A Blue Cross and Blue Shield Association Presentation

Payer Perspectives on Improving Medication Safety

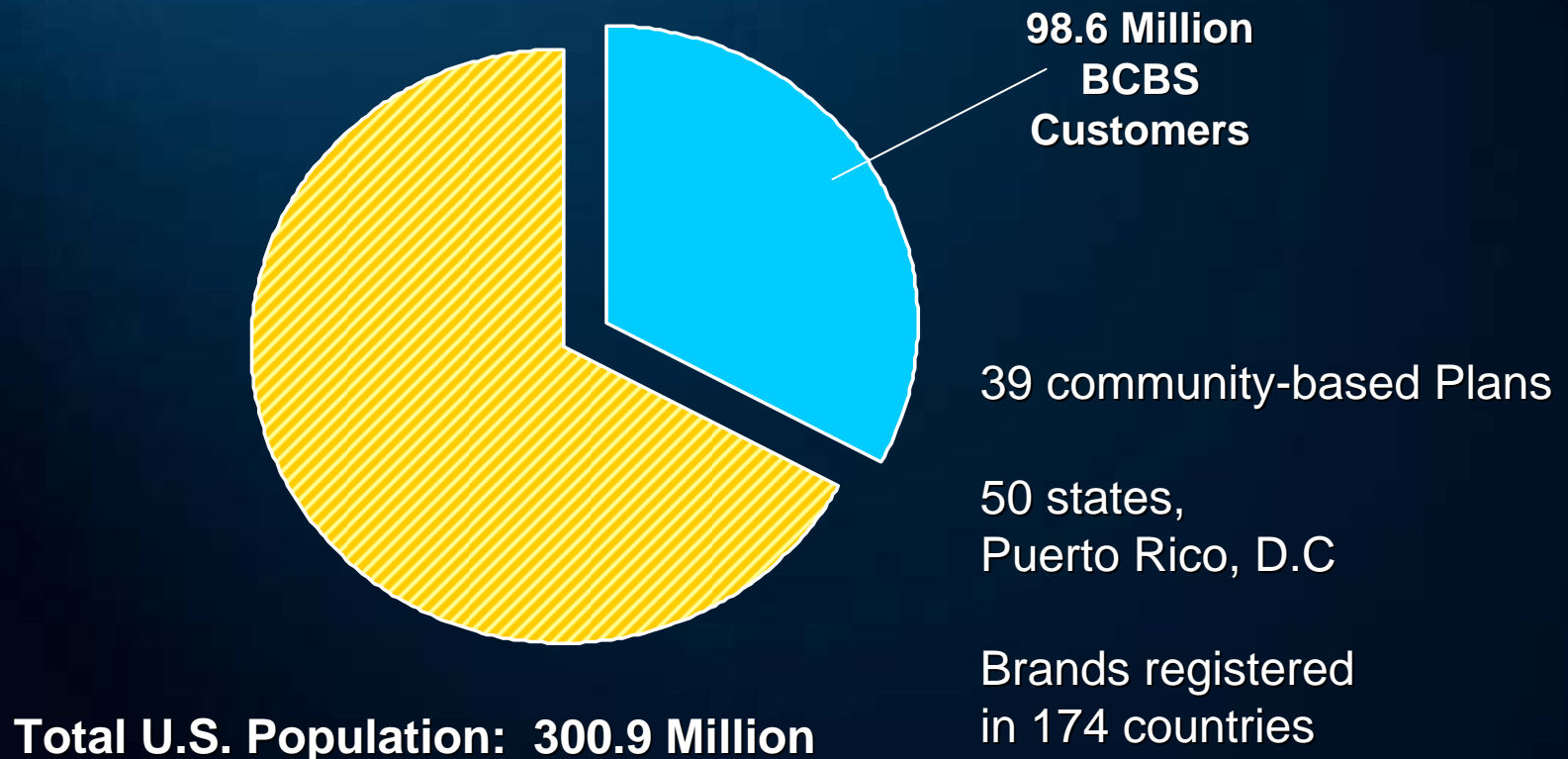
**Implementation of Risk Minimization Action Plans
(RiskMAPs) to Support Quality Use of Pharmaceuticals**

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The Blue System Today

Nearly one-in-three Americans — about 33 percent — receive their health insurance through a Blue Cross and Blue Shield Health Plan.

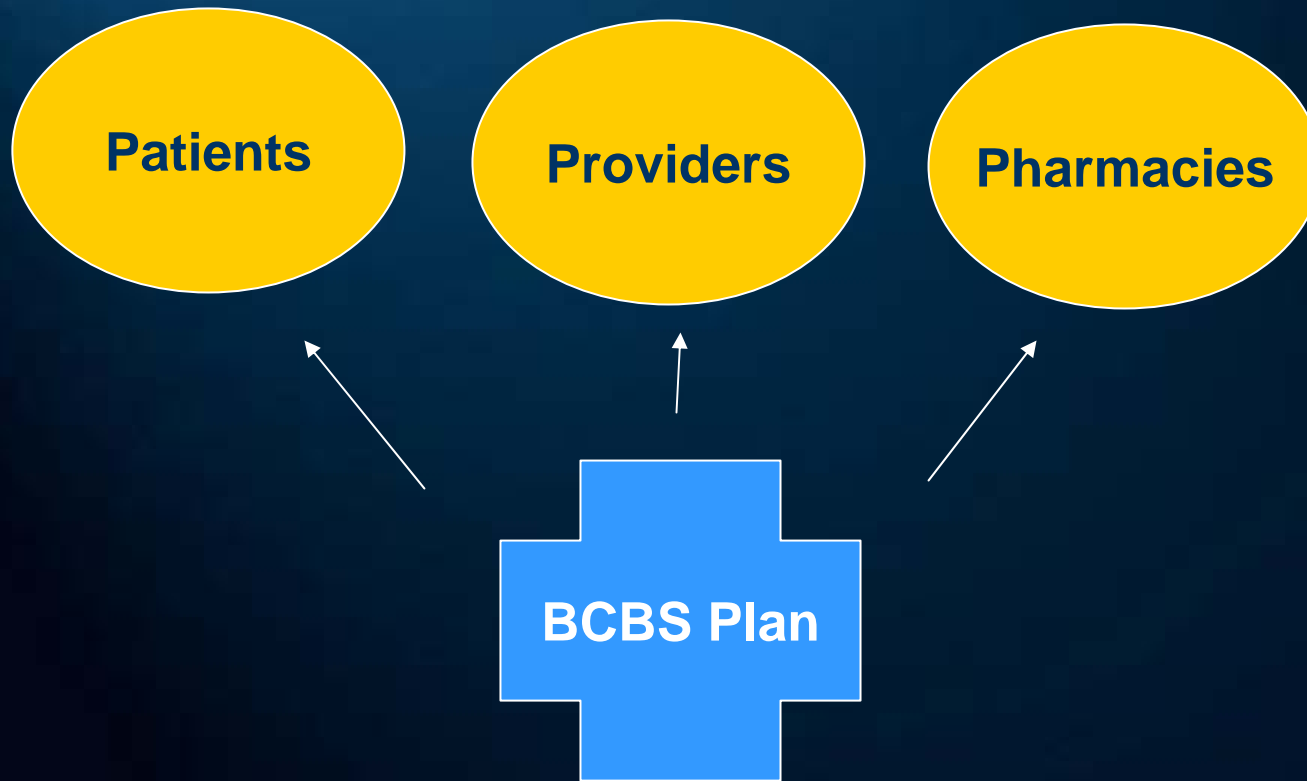


Blue System Commitment to Medication Safety

BCBSA and Member Plans have endorsed Guiding Principles for Blue Cross and Blue Shield Prescription Drug Benefits. We believe in:

- **Evidence-based** practice in the use of pharmaceuticals
- Choices of effective medications for our members based on **clinical evidence and expert consensus** by independent Pharmacy and Therapeutics Committees
- **Physicians'** ethical obligation to assume primary accountability for appropriate individual therapy
- **Integrated pharmacy and medical data and management** supporting the delivery of coordinated care
- **Education** for members, prescribers, caregivers, and dispensing pharmacists to enhance appropriate use and compliance

Health Plan Relationships



BCBS Plan Initiatives at the Point of Sale

- 89% of BCBSA Plans responding to a recent survey are implementing initiatives at the point of sale to improve medication safety
- The most commonly used initiatives are:
 - Edits for dose or maximum units (82%)
 - Edits for gender, age, duplication (79%)
 - Monitoring for contraindicated drugs and combinations (71%)
 - Drug Utilization Review (75%)

Evidence-Based Medication Policies and Formularies

- Through deliberations of independent Pharmacy and Therapeutics (P & T) Committees
- Include FDA-approved indications and appropriate off-label indications
 - For Off-label: ensure adequate evidence either in clinical literature or compendia listings
- Benefit design-tier placement, co-payments
- Policies contain appropriate use criteria
 - Indications
 - Concomitant and/or failed therapies (step therapy)
 - Dosing guidelines
 - Reevaluation parameters for continued use
 - Non-covered Indications-Prior Authorization

BCBS Plans Communicate with Physicians on Safety Concerns

- To notify them of new black box warnings or recalls and patients on the drugs at issue
- Plans monitor pharmacy claims data for adherence and communicate to physicians on refill compliance
- Plans monitor claims to assure compliance with required tests
- Physicians notified of DUR issues- duplicate therapy, high dosage, contraindications

BCBS Plans Communicate with Members

- Plans inform affected members of drug recalls and new black box warnings
- Many Plans provide medication information on websites or through newsletters and disease management programs

How Do Blue Plans Work With RiskMAPs?

- The majority of BCBS Plans are interested in obtaining information about current and new RiskMAPs so they can incorporate the information in managed prescription benefit programs.
- A number of Plans currently do so.
- Some Plans feel they lack current information on RiskMAPs and would like to see FDA develop a **central repository** of RiskMAPs accessible to the public.

Use of RiskMAPs to Manage Pharmacy Benefits

- When RiskMAPs are known, BCBS Plans may use them as the **starting point** for benefits management.
- In some instances, RiskMAP procedures are adopted by the BCBS Plan as sufficient to assure safety of drug use.
- Plans may be in a position to implement **use management programs** that FDA cannot impose. If a drug is risky and requires a RiskMAP, some BCBS Plans may require trial of a less risky drug from the same therapeutic class before approving payment for a RiskMAP drug.

Plan Reinforcement of RiskMAPs

- Plans can use elements of RiskMAPs in on-line edits at the point of sale
- One Plan builds from RiskMAPs. Example: Tysabri
 - Drug may be acquired through a vendor who provides practitioner certification to Plan
 - Drug not used as first line due to safety concerns
 - When coverage of drug is approved, dose and interval guidelines may be imposed by Plan
 - Medical management integrated with pharmacy management-contraindicated drugs are blocked in adjudication when Tysabri is approved

Impact of Electronic Prescribing/EHR

- Electronic Prescribing and automated lab results reporting will reduce reporting burden
- e Rx linked to patient records will issue automatic alerts for contraindicated drugs, drug-drug interactions, quantity and dose limits, duplication
- Enhanced opportunity for clinical decision support
- Enables patient-specific adherence reporting
- Refills can be blocked where appropriate
- Many BCBS Plans have made efforts to support eRx

Challenges of the Current System

- Need for objective **consumer education** on disease states and risks and benefits of drugs
- DTC does not adequately address effectiveness, risk, and alternative therapies
- **More safety information is needed** by clinicians, patients, and payers post-approval
- **Comparative effectiveness information** is needed
- **Care coordination** and medical home needed

Possible Role for Health Plans

- **Use** RiskMAP tools in managing pharmacy benefits
- **Expand** reach of educational and reminder programs
- **Align** with prescribing and dispensing restriction programs to support FDA goals and minimize duplication/confusion
- **National pharmacovigilance system** can be built in collaboration with payers who have large pharmacy and medical claims databases
- **Help evaluate** compliance and effectiveness of RiskMAP program elements