GLOBAL MEDI-CAL DRUG USE REVIEW (DUR) BOARD MEETING AGENDA

State of California
DEPARTMENT OF HEALTH CARE SERVICES

Notice is hereby given that the **Global Medi-Cal DUR Board** will conduct a public meeting on **Tuesday, May 17, 2022,** at the following location:

Department of Health Care Services
1700 K Street
1st Floor Conference Room
Sacramento, CA 95814
9:30 AM – 2:00 PM
All times shown are approximate and are subject to change
Registration link to attend meeting via webinar

Report Type*	Agenda Item	Presenter	Time
C	**1.** Welcome/Announcements/Introductions/Roll Call	Pauline Chan, RPh, MBA	930-940
I/D	**2.** Call to Order/Guidelines/Robert's Rules	Yana Paulson, PharmD	940-945
R/A/D	**3.** Review and Approval of Previous Minutes from February 15, 2022	Yana Paulson, PharmD	945-950
	4. Old Business		
R/I/D	**a.** DHCS Update **b.** Review of Board Action Items from February 15, 2022 **c.** Recommended MCP Action Items from February 15, 2022	Pharmacy Benefits Division Pauline Chan, RPh, MBA	950-1055
Morning Break			1055-1100
	5. New Business		
R/I/D	**a.** Health Plan Presentation by Alameda Alliance for Health: Pharmacy Programs	Helen Lee, PharmD, MBA [Alameda Alliance for Health]	1100-1145
A/D	**b.** Global DUR Board Activities i. Vital Directions Framework: 2021 Update	Yana Paulson, PharmD	1145-1200
Lunch Break			1200-1245

Report Type*	Agenda Item	Presenter	Time
R/D	**c.** Recap of morning action items	Hannah Orozco, PharmD	1245-1250
R/A/D	**d.** UCSF Update i. Review of DUR Publications ii. DUR Educational Outreach to Providers iii. Retrospective DUR iv. Prospective DUR	Shalini Lynch, PharmD, Amanda Fingado, MPH, and Ally Diiorio, PharmD	1250-145
R/D	**e.** Looking ahead: Call for future meeting agenda topics	Yana Paulson, PharmD	145-150
C	**6.** Public Comments **		150-200
I	**7.** Consent Agenda		
	a. Meeting feedback **b.** Next meeting: Tuesday, September 13, 2022 1700 K Street 1st Floor Conference Room Sacramento, CA 95814 **c.** Proposed DUR Board Meeting Dates for 2022/2023: Tuesday, November 15, 2022 Tuesday, February 28, 2023 Tuesday, May 16, 2023 Tuesday, September 19, 2023 Tuesday, November 28, 2023		
	8. Adjournment		200

* REPORT TYPE LEGEND: **A: Action**; **C: Comment**; **D: Discussion**; **I: Information**; **R: Report**

** Comments from the public are always appreciated. However, comments will be limited to five minutes per individual.

Picture identification is required to gain access into the California Department of Health Services building. However, your security information will not be provided to the Global DUR Board.

You can obtain the Global DUR Board agenda from the Medi-Cal DUR Main Menu Web site (http://files.medi-cal.ca.gov/pubsdoco/dur/dur_home.asp).

GLOBAL MEDI-CAL DUR BOARD MEETING
PACKET SUMMARY
May 17, 2022

- **Suggested Sections to Review Prior to Meeting:**
  - Review the updated Vital Directions for Health and Health Care: Priorities for 2021 (**Pages 35 – 41**)
    - As the Board has motioned to let the Vital Directions Framework inform the work of the Global Medi-Cal DUR Board, it is important to review the updates made by the authors of the Framework. Please review this article in advance of the meeting and be ready to share any thoughts and/or suggested edits to the Board Goals for 2022.

  - FFY2021 DUR Annual Report to CMS (**Pages 70 – 120**)
    - This version of the FFS DUR Annual Report to CMS covers FFY2021, which is between October 1, 2020, and September 30, 2021. This report is due to CMS via the web portal submission process by June 30, 2022. Please review this report in advance of the meeting and be ready to share any suggested edits or corrections.

- **Important Reminders:**
  - The following dates have been posted for the remaining 2022 DUR Board meetings:
    - Tuesday, September 13, 2022
    - Tuesday, November 15, 2022

  - The following tentative dates have been proposed for the 2023 DUR Board meetings:
    - Tuesday, February 28, 2023
    - Tuesday, May 16, 2023
    - Tuesday, September 19, 2023
    - Tuesday, November 28, 2023

Global Medi-Cal DUR Board General Meeting Guidelines

- Be familiar with the Bagley-Keene Open Meeting Act
- Be familiar with Robert's Rules of Order
- Be courteous, respectful, and open minded of other's comments
- Be prepared by reviewing materials and downloading documents in advance
- The meeting will not be cancelled if there are unforeseen technical difficulties or limitations with the webcast
- For those viewing the meeting via webcast, please use the chat feature to ask questions

Robert's Rules of Order

Purpose:

- Supports an orderly and democratic decision process
- Facilitates group decisions

Motion:

- A member presents a formal proposal requesting the group to take a certain action or position
- A main motion is required to begin the decision-making process
- A motion occurs prior to discussion

The Main Motion Process

1. Member makes a **clearly worded motion to take action on a position.**
   - "I move that…..". Motion is recorded in minutes.
2. **Motion must be seconded**. A motion without a second does not move forward.
   - "Second!" A second allows discussion to occur; it does not signify approval.
3. **Chairperson restates the motion.** This provides clarity**.**
   - "It is moved and seconded that….."
4. **Discussion/debate occurs.**
   - Maker of motion starts discussion.
   - If amendments offered – return to step 1 to amend motion: "I move to amend the motion by….."
5. Chairperson closes discussion and **states the question/asks for a vote.**
   - "The question is on the adoption of the motion that…."(Repeat the motion word for word).
6. **Chairperson provides voting directions: "**Those in favor of the motion, say aye", "those oppose, say no".
7. **Chairperson announces the result of the vote**: The "ayes have it, and the motion is adopted" or "the nos have it, and the motion is lost". Recorded in minutes.

Medi-Cal DUR

What to Say

Purpose	Motion	Say	Debate allowed	Vote Required
Introduce business	Main	"I move that…"	Yes	Majority
Second a Motion	Second	"Second."	No	No
Change the wording/clarify a motion	Amend	"I move to amend the motion by…."	Yes	Majority
Postpone action until a specific time	Postpone	"I move the motion be postponed until…"	Yes	Purpose
Take break	Recess	"I move to recess for (x) minutes."	No	Majority
Close meeting	Adjourn	"I move to adjourn."	No	Majority

Medi-Cal DUR

GLOBAL MEDI-CAL DRUG USE REVIEW (DUR) BOARD
MEETING MINUTES
Tuesday, February 15, 2022
9:30 a.m. – 12:30 p.m.

Location: WebEx Only

Topic	Discussion
1) WELCOME/ INTRODUCTIONS/ ROLL CALL/ ANNOUNCEMENTS	• Board members present on the webinar included Drs. Timothy Albertson, Michael Blatt, Lakshmi Dhanvanthari, Jose Dryjanski, Stan Leung, Johanna Liu, Janeen McBride, Robert Mowers, Yana Paulson, Randall Stafford, Marilyn Stebbins, Vic Walker, and Andrew Wong. • Board members absent: None. • Department of Health Care Services (DHCS) Pharmacy Benefits Division employees present on the webinar included Harry Hendrix, the Chief of Pharmacy Benefits Division, and Chris Amaral, PharmD, Pauline Chan, RPh, MBA, Jeanette Kao, PharmD, Donnie Minor, PharmD, Katherine Nguyen, PharmD, Paul Nguyen, PharmD, Paul Pontrelli, PharmD, Emily Schulz, PharmD, Victoria Tereschenko, PharmD, Ivana Thompson, PharmD, Jose Villalobos, MPA, and Mike Wofford, PharmD. • Representatives from Medi-Cal managed care plans (MCPs) present on the webinar included Clarence Chung, PharmD, MBA (Kaiser), Anthony Dao (AIDS Healthcare Foundation), Mayur Domadia, PharmD (UnitedHealthcare Community Plan of California), Biyan Feng, PharmD (Health Plan of San Mateo), Matthew Garrett, PharmD (Health Plan of San Joaquin), Kris Gericke, PharmD (CalOptima), Evangelina Hurtado, PharmD (Anthem) Adam Horn, PharmD (CenCal Health), Jeff Januska, PharmD (CenCal Health), Rebecca Lau, PharmD (Contra Costa Health Plan), Susan Nakahiro, PharmD (Blue Shield of California Promise Health Plan), Jessica Shost, PharmD (San Francisco Health Plan), Flora Siao, PharmD (California Health & Wellness), Ashley Teijelo, PharmD (Community Health Group), Bruce Wearda, RPh (Kern Family Heath Care), Johnathan Yeh, PharmD (Health Plan of San Joaquin). • Ms. Chan established there was a quorum for this meeting and acknowledged the Executive Order is still in place to allow this meeting to be held in a virtual format until permitted otherwise, due to the coronavirus disease 2019 (COVID-19) pandemic.
2) CALL TO ORDER/ GUIDELINES/ ROBERT'S RULES	The Chair of the Board, Dr. Yana Paulson, called the meeting to order. Dr. Paulson reviewed the meeting guidelines and stated that everyone is expected to be courteous, respectful, and open-minded. Dr. Paulson then provided a summary of Robert's Rules of Order.
3) REVIEW AND APPROVAL OF PREVIOUS MINUTES FROM NOVEMBER 16, 2021	The Board reviewed the minutes from the Board meeting held on November 16, 2021. Dr. Wong had suggested several minor corrections to the minutes. Dr. Albertson motioned that the minutes be approved with Dr. Wong's edits incorporated. Dr. Stebbins seconded the motion. There was no discussion. The Board voted to approve the minutes. **AYE:** Albertson, Dhanvanthari, Dryjanski, Leung, Liu, McBride, Mowers, Paulson, Stebbins, Walker, and Wong **NAY:** None **ABSTAIN:** None **ABSENT:** Blatt and Stafford **ACTION ITEM**: Post the November 16, 2021, minutes to the DUR website.

4) OLD BUSINESS	**a.** DHCS Update – Mr. Hendrix provided an update on the transition to Medi-Cal Rx, which took place on January 1, 2022. Mr. Hendrix acknowledged that DHCS is aware of challenges and difficulties related to call center issues and timely adjudication for prior authorizations (PAs). Mr. Hendrix explained that lack of experience and staffing issues due to COVID-19 are contributing factors to the challenges at the call center, which include significant hold times and difficulty providing timely and appropriate resolutions. Mr. Hendrix shared that DHCS has enlisted their own call center to help resolve calls that don't require access into the Magellan (MMA) system, such as issues with eligibility and beneficiary card issues. Mr. Hendrix stated that MMA will be hiring an additional 120 employees by the end of February and an additional 70 employees by the end of March. He also explained they plan to address the lack of experience in the MMA call center by increasing training and focusing efforts to streamline resolutions at the call center. Mr. Hendrix then stated that PAs are the highest driver of inquiries to the call centers, representing about 70% of all calls from pharmacies, prescribers, and beneficiaries. He noted that many of the DUR edits were not in place with the old system, which resulted in confusion regarding reject codes and overrides at the pharmacy. Mr. Hendrix stated that to alleviate this issue, DUR alerts have been temporarily modified to DUR messages that do not require an override. Mr. Hendrix stated that to reduce PA volume and assist in resolution of issues, DHCS also brought on 31 full-time employees in January 2022. Mr. Hendrix reported that these strategies have resulted in an 80% reduction of PA volume, and as of February 14th, MMA is now reaching the 24-hour target response time for new PAs. Mr. Hendrix shared that both DHCS and MMA are moving forward with an aggressive education and outreach plan to train providers on the DUR edits, including which medications need a PA under the 180-day transition policy. Mr. Hendrix also reported there has been confusion around emergency fills; therefore, the policy was updated to allow pharmacies to provide a 14-day supply for emergency fills (rather than 72 hours), with no PA required and guaranteed payment if the request is under the emergency fill protocol and the medication is a covered benefit. Dr. Paulson asked if DHCS would be able to provide a report to the Board that indicates the results of lifting PAs (including the total number of DUR edits that have been modified) to get a better idea of how the benefit was administered during this transition. Mr. Hendrix responded that he would take this request back to DHCS for consideration to see what can be provided. Dr. Dryjanski asked if all the edits and changes can be summarized in a written document to better visualize what has occurred. Mr. Hendrix noted that when there are changes to rules or edits, an alert is sent out via the Medi-Cal Rx Subscription Service (MCSS), and a summary of all alerts is sent out at the end of each month. Mr. Hendrix encouraged everyone to sign up for the MCSS, if they haven't already. Dr. Schulz added the following link to sign up for MCSS in the chat: https://mcrxsspages.dhcs.ca.gov/Medi-CalRxDHCScagov-Subscription-Sign-Up. Dr. Leung asked if prescriptions that have been allowed temporary coverage will have to be submitted for a PA starting on May 1st. Mr. Hendrix clarified that the May 1st date was in reference to when the DUR edits will resume, and that the PA requirement currently does not have an end date set. Dr. Thompson noted that the DUR edits are not removed, but rather they have been modified to soft edits as DUR messages. She added that DUR messages still show up on the pharmacy's screen and that UCSF plans to report on the message-only data at the next DUR Board Meeting. Dr. Nakahiro asked via the webinar chat feature what the plan is to re-introduce edits and PA requirements. Mr. Hendrix explained that there is not a date set to re-introduce the PA requirements, but there is a plan to re-phase in the edits after robust education and outreach to pharmacies and prescribers regarding what the edits mean and what to do with them. Dr. Siao commented via the webinar chat feature that they have received questions from providers regarding where to find drug-specific PA criteria on the Medi-Cal Rx webpage and asked if providers need to call MMA to find out PA requirements for specific drugs. Dr. Thompson replied that drug-specific PA criteria are not published online, which has

always been the case with Medi-Cal. Dr. Thompson noted that providers enrolled with CoverMyMeds are able to view the general questions asked for the PA, and based on their responses, the PA could be approved right away. Dr. Thompson shared that if the PA criteria are not met, the request is moved over to the manual workstream. Dr. Thompson added that prescribers do not need to call for approval, although if a drug is requested for an off-label indication and some criteria are not met, providers will need to explain why and support medical necessity.

Joe Payne, RPh (Horizon Therapeutics) asked via the webinar chat feature if Mr. Hendrix could address physician administered drugs (PAD) and whether they are approved through the medical or pharmacy benefit. Mr. Hendrix responded that all PADs are covered as a medical benefit, but there are a few instances where PADs can be billed through the pharmacy benefit as well. Mr. Hendrix explained that if a PAD is provided and administered in physician's office, it is billed as a medical claim. Dr. Leung commented there may need to be a discussion about grey areas, such as self-administered drugs given in the provider's office, particularly regarding package size. Dr. Wofford added that per the Social Security Act, when a drug is administered in a medical setting, it is not a pharmacy benefit. Dr. Leung asked if PA approval can depend on if a patient has tried certain medications before. Dr. Thompson responded that there are no step therapy requirements in Medi-Cal, and a project is underway to streamline the questions in CoverMyMeds. Dr. Thompson added that providers may have to answer questions about prior medication trials, but the provider can answer no and coverage will not depend on if the patient has tried other medications.

Dr. Domadia asked via the webinar chat feature what the process will be for beneficiaries that do not need a PA currently because the edit was removed but will need a PA when the edit resumes. He wondered if once the PA edits resume, hundreds of thousands of claims could be dropped at the same time and create the same burden that existed at the start of go-live. Mr. Hendrix reiterated the phased implementation strategy will only occur after education and outreach to pharmacies and providers, with the approach clearly articulated before it happens. Dr. Blatt noted there were multiple forums leading up to go-live and asked what will be different between last time and this time. Dr. Thompson stated that the difference is now Medi-Cal Rx is live. She noted that Mr. Hendrix previously discussed the short-term resolutions and there are additional long-term solutions being worked on as well.

Dr. Paulson asked if there would be a way for plans and providers to communicate feedback regarding edits and alerts to Medi-Cal Rx. Dr Leung suggested there may be an opportunity for the Board to provide recommendations and input, such as providing reviews and comments on criteria. Dr. Thompson indicated that DHCS would take these recommendations back.

Finally, in response to several questions sent via the webinar chat feature, Dr. Paul Nguyen provided the link to the Medi-Cal Rx Contract Drugs List and shared that if there were any further questions DHCS would respond via email. Mr. Hendrix encouraged additional questions to be asked during the regularly scheduled health plan calls or on the related forums.

b. Review of Board Action Items:

- Medication Therapy Management (MTM) Program Updates – Dr. Wofford provided an update on the MTM program, which launched in December 2021. Dr. Wofford shared that MTMquestions@dhcs.gov was developed by DHCS as a portal for communication specific to MTM, and anyone with questions about the MTM program or who is interested in becoming a MTM provider can use this to interact directly with DHCS staff. Dr. Wofford indicated that DHCS is pleased with the initial interest in the MTM program and shared that there have been about 120 applications submitted to the MTM program, with 9 denied and 30 approved. He noted that the remaining applications are currently under review or are awaiting additional information from applicants. Dr. Wofford stated that for

	now, MTM services are limited to five therapeutic categories, but other categories are being considered for addition in the future. He added that DHCS will contract with any provider who will agree to the obligations of the MTM contract, which includes identifying at-risk beneficiaries who may benefit from MTM, providing services to those beneficiaries, and meeting documentation and reporting requirements to ensure compliance with the contract. Dr. Wofford then introduced Dr. Tereschenko, who was integral to the roll out of the MTM program but has now been promoted to another branch within the division. Dr. Tereschenko added that interest in the program is picking up and more applications continue to be submitted. Dr. Paulson asked how long it takes for an MTM application to be approved. Dr. Tereschenko indicated that it depends on the volume of applications and how quickly the pharmacy provides any needed follow-up documentation. Dr. Tereschenko estimated that it currently takes about a week for approval, but it really depends on volume and application completeness. Dr. Leung asked if there was data on how many MTM claims have been submitted thus far. Dr. Wofford replied that as of a couple of weeks ago, no claims had been adjudicated, but this is to be expected as it takes time to identify beneficiaries, schedule appointments, provide services, and complete the claim submission process. Dr. Leung asked where most of the applications are coming from and if Medi-Cal plans to post information on how members can find pharmacies that offer MTM. Dr. Tereschenko stated that most applications are coming from independent pharmacies, with a few applications from specialty pharmacies. Dr. Wofford stated that pharmacies should be identifying beneficiaries at risk instead of MTM initiated by the patient, but DHCS might consider posting a list of pharmacies. Dr. Leung commented that plans could identify patients as well and make referrals if they were provided a list of pharmacies that offer MTM. Dr. Wofford responded that once there is a better sense of pharmacy participation, this information will be shared with plans. Dr. Paulson added that providers who prescribe specialty drugs might choose to refer beneficiaries to a pharmacy who provides MTM services. Dr. Wofford stated that DHCS will take this into consideration. Dr. Blatt offered his congratulations to DHCS on launching the MTM program and asked if the service must be provided by a pharmacy with a NPI and if health system ambulatory care pharmacies can apply using the outpatient pharmacy NPI. Dr. Wofford responded that the State Plan Amendment (SPA) limits the MTM program to enrolled pharmacy providers, so if these criteria are met, they can apply. **c.** Recommended Action Items for MCPs from November 16, 2021 – Ms. Chan presented the recommended action items for MCPs from the Board meeting held on November 16, 2021. Recommendations are separated into two categories: required action items and suggested action items. **d.** Annual DUR Report to CMS: Summary of FFY 2020 MCO Survey – Ms. Chan reported that there are two state comparison summaries available on the Centers for Medicare & Medicaid Services (CMS) website, the National Medicaid Fee-For-Service (FFS) 2020 Drug Utilization Review (DUR) and the National Medicaid Managed Care Organization (MCO) 2020 Drug Utilization Review (DUR). Ms. Chan then provided a summary of the MCO state comparison summary. Ms. Chan noted that the survey for FFY 2021 has not yet been released by CMS but is expected by April 1, 2022.
5) NEW BUSINESS	**a.** Global DUR Board Activities i. Annual Review: 2021 – Ms. Chan acknowledged the contributions of Johanna Liu, PharmD, MBA, as the outgoing DUR Board Chair. Dr. Liu went through the Board

accomplishments during 2021, which included submitting a letter of support for AB 885 to broaden the public's access to DUR Board proceedings while also providing cost savings to the State and reducing the Board's carbon footprint. Dr. Liu also acknowledged that the Board submitted a medication therapy management (MTM) petition to DHCS that contributed to the adoption of a hybrid proposal between the Board's position and comprehensive medication management (CMM). Dr. Liu noted that the SPA 21-0028 was approved on Sept 15, 2021, and the MTM program officially launched in December 2021. The Board shared their appreciation of Dr. Liu's leadership during this challenging year.

ii. Board Goals: 2022– Dr. Paulson shared the following Board goals for 2022:

- Advise DHCS on updates/additions to existing Drug Utilization Review reports through Medi-Cal Rx
  - Collaborate with Magellan to explore new system capabilities
  - Focus on medication safety and effective use
- Continue to promote dialogue and collaboration with MCOs
  - Present innovative practices and projects
  - Share lessons learned
  - Disseminate DUR Educational Bulletins and Outreach Letters
  - Integrate/align DUR Actions
- Conduct DUR activities after full implementation of the SPA for the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act
- Continue to focus on the top three DUR priority areas established in 2018-2019, *using the new capabilities available once Medi-Cal Rx is implemented*
  - Optimizing drug prescribing and dispensing, including specialty drugs
  - Optimizing medication management, prevention, and wellness for chronic conditions, with a special focus on diabetes, hypertension, depression, and anxiety
  - Optimizing pain management and use of opioids
  - Continue to use Vital Directions framework as a guide
- Continue to engage with DHCS on programs related to DUR activities, including the following:
  - California Advancing and Innovating Medi-Cal (CalAIM)
  - DHCS Comprehensive Quality Strategy
  - Medication Therapy Management Services
    - Support and promote MTM to achieve > 90% adherence for specialty medications
    - Identify barriers to the provision of MTM services

Dr. Leung stated that it might be helpful if the goals for MTM adherence included non-specialty medications as well, for example, statins for diabetes or cardiovascular disease. Dr. Leung motioned to include all medications within the framework of MTM and to monitor the effectiveness of the MTM program for chronic conditions. The motion was seconded. Dr. Wong added a motion to expand the description of the Vital Directions Framework listed in the goals to include a summary of the following four essential infrastructure needs:

1. Measure what matters most
2. Modernize skills
3. Accelerate real-world evidence
4. Advance science

There was no further discussion. The Board approved both modifications to the Board goals for 2022.

AYE: Albertson, Blatt, Dhanvanthari, Dryjanski, Leung, Liu, McBride, Mowers, Paulson, Stafford, Stebbins, Walker, and Wong
NAY: None
ABSTAIN: None

ABSENT: None

ACTION ITEM: The DUR Board recommendation to modify the Board goals for 2022 to include monitoring the effectiveness of the MTM program for chronic conditions will be submitted to DHCS.

AYE: Albertson, Blatt, Dhanvanthari, Dryjanski, Leung, Liu, McBride, Mowers, Paulson, Stafford, Stebbins, Walker, and Wong
NAY: None
ABSTAIN: None
ABSENT: None

ACTION ITEM: The DUR Board recommendation to expand the description of the Vital Directions framework to include the four essential infrastructure needs will be submitted to DHCS.

b. California Advancing and Innovating Medi-Cal (CalAIM) Presentation by Palav Barbaria, MD, MHS (Chief Quality Officer and Deputy Director of Quality and Population Health Management, DHCS) – Dr. Barbaria provided an overview of the vision and the comprehensive quality strategy for CalAIM, which is being described as a long-term commitment to transform Medi-Cal. Dr. Barbaria noted that there are numerous initiatives that tie back to each of the quality strategy goals, which include 1) engaging members as owners of their own care, 2) keeping families and communities healthy via prevention, 3) providing early interventions for rising risk and patient-centered chronic disease management, and 4) providing whole person care for high-risk populations and addressing social drivers of health.

Dr. Paulson asked how patients can be engaged as owners of their own health and if there are any plans to provide education and training for members. Dr. Barbaria clarified they are considering factors such as literacy levels and stated there are initiatives designed to provide support for beneficiaries through health education, navigation, and prevention. Dr. Stafford applauded this endeavor and encouraged the group to think beyond education, as more information alone doesn't make a difference; rather, when patients take that knowledge and are motivated to act as owners of their own health, change may occur. Dr. Stafford asked for recommendations on how to improve patient motivation. Dr. Barbaria agreed that there is a need to think about health empowerment, although that can be a tough uphill battle to get to the roots of the power dynamic and change the culture. Dr. Barbaria indicated that some of the change starts with the patient bringing their own voice.

Dr. Barbaria reported that the long view of health and wellness needs more investment in prevention, with areas of focus being children's preventive care, behavioral health integration, and maternity outcomes and birth equity. Dr. Babaria then reviewed health equity domains and shared the Bold Goals Initiative, which ensures that all health plans exceed the 50th percentile for all children's preventive care measures by 2025. She noted that all programs need to capture disability status and sexual orientation/gender data, with the goal to have better data and reduce disparities across the entire Medi-Cal population. Ms. Chan talked about the importance of data and the focus on measuring what matters most. Ms. Chan asked Dr. Barbaria what advice she had for the DUR board to increase the selection of data that measures what matters. Dr. Barbaria stated they are moving in the right direction, and everything should be actionable. She added that data that is not acted upon should not be collected, and she encouraged the Board to consider how quality measurements can be aligned so that everyone has an incentive to work together.

Dr. Stafford noted that one of the big challenges is what to do about institutional racism, which is often fundamental in many health care systems where there is great differentiation on where people go to receive care. Dr. Barbaria suggested a multi-level approach that uses the right data to ask and answer the right questions. She noted

significant disparities even within the Medi-Cal population, where different insurance plans may have different distributions of wealth among their beneficiaries. She added that even within counties there may be disparities, such as the 20 – 40% disparity seen for COVID vaccination between Medi-Cal beneficiaries and all other county residents. Dr. Barbaria also indicated that at the hospital level, there are predictive scores and there are often differences seen by race in those expected outcomes. Dr. Wong asked how to prevent inequities in rheumatologic disease management. Dr. Babaria responded that prevention is key and that we need to restructure our chronic disease programs to be patient-centered and leverage our formulary to ensure guidelines are followed. Dr. Barbaria stated that for those with advanced disease, they need to be able to access enhanced care management services, and programs need to identify people with worsening disease before it hits a critical point.

Both Dr. Dryjanski and Dr. Stafford thanked Dr. Barbaria for the presentation. Dr. Stafford suggested formalizing the collaboration between the DUR Board and CalAIM, adding that medications and vaccinations are key strategies for prevention goals. Dr. Barbaria welcomed this suggestion. Dr. Stafford pointed out that the Board's mission is well beyond pharmacy decision making and formulary construction. Dr. Stebbins recommended that CalAIM embrace pilot models to care for patients in the community with chronic conditions. Dr. Stebbins stated there are good models currently, but there needs to be enhancement. Dr. Barbaria agreed and added that new benefits such as doulas and community health care advocates contribute to these efforts. Via the webinar chat feature, Dr. Barbaria shared the links to both the DHCS Comprehensive Quality Strategy and the DHCS COVID-19 Response.

c. UCSF Update

i. Review of DUR Publications

- Shalini Lynch, PharmD (UCSF) reported that DUR educational articles are now located on the Medi-Cal Rx DUR website. Dr. Lynch noted that the last three articles have been formatted and published with Medi-Cal Rx branding and all other previously published DUR educational articles are on track to move into an archive folder on the Educational Articles page by February 25, 2022. Dr. Lynch stated that once this transition is complete, all previous DUR web pages and links not affiliated with Medi-Cal Rx will no longer be active.
- Dr. Lynch shared that the DUR educational bulletin Improving the Quality of Care: Legislative Impact on the Use of Naloxone published in December 2021. Dr. Lynch noted there is also an IRB submission pending review in this area for additional dissemination of findings to a broader research audience.
- Dr. Stafford asked via the webinar chat feature if there is any information on why naloxone appears to be less effective for overdoses associated with fentanyl contamination. Dr. Albertson stated that his experience at the California Poison Control System suggests that naloxone works well for fentanyl overdose, regardless of the source of fentanyl. Amanda Fingado, MPH (UCSF) also shared that some reports out of San Francisco suggest that when the stay-at-home order was in place at the start of the pandemic, more people were alone at the time of an overdose and may not have had others with them, preventing administration of fentanyl and/or notification of emergency services in a timely fashion.
- Discussion/recommendations for future educational bulletins – The calendar for future DUR educational bulletins was reviewed. There were no changes suggested.

ii. Prospective DUR: Fee-for-Service

- Review of DUR Alerts for New Generic Code Numbers (GCNs) in 4Q2021 (October – December 2021): At each Board meeting, a list of new GCN additions with prospective DUR alerts turned on other than DD, ER, and PG are provided to the Board for review. At this meeting, the Board reviewed the alert profiles for the following drugs:
  - AVACOPAN – Drug-Disease (MC)
  - BICTEGRAV/EMTRICIT/TENOFOV ALA – Ingredient Duplication (ID)

- CABOTEGRAVIR – Ingredient Duplication (ID)
- CELECOXIB – Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- DICLOFENAC POTASSIUM – Drug-Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- LOVASTATIN – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Ingredient Duplication (ID), Drug-Age (PA), High Dose (HD), Low Dose (LD)
- NIRMATRELVIR/RITONAVIR – Ingredient Duplication (ID)
- PHENOBARBITAL – Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), High Dose (HD), Low Dose (LD)
- SERTRALINE HCL –Therapeutic Duplication (TD), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)

There were no questions or objections to these alert profile recommendations.

iii. Retrospective DUR

- FFY 2021 DUR Annual Report to CMS: Additional Data – Ms. Fingado presented data for FFY 2021 that she thought the Board might find useful. Data reported included fee-for-service pharmacy utilization by age group, the top 20 drug therapeutic categories by utilizing beneficiaries, the top 20 drugs by utilizing beneficiaries, and trends over time in generic utilization and generic expenditures. Ms. Fingado also noted the complete draft annual report covering the Medi-Cal fee-for-service program for FFY 2021 will be included in the Board packet for the May meeting, as the final survey has not yet been released by CMS.

- Global Quarterly: 3Q2021 (July 2021 – September 2021) – Ms. Fingado presented the Global Quarterly Medi-Cal DUR report for 3Q2021. This quarterly report contains all pharmacy utilization data for the Medi-Cal program. Utilization data are presented in aggregate, and then stratified by FFS or MCP enrollment status and the following population aid code groups:
  - Affordable Care Act (ACA)
  - Optional Targeted Low-Income Children (OTLIC)
  - Seniors and Persons with Disabilities (SPD)
  - All other aid codes not categorized as ACA, OTLIC, or SPD (OTHER)

  The Board had no questions and there was no discussion.

- FFS Quarterly Report: 4Q2021 (October 2021 – December 2021) – Ms. Fingado presented the Medi-Cal fee-for-service quarterly DUR report for the 4th quarter of 2021, which includes both prospective and retrospective DUR data. This quarterly report contains fee-for-service pharmacy utilization data presented in aggregate, and then stratified by Medi-Cal FFS enrollees only and by Medi-Cal MCP enrollees only. This report includes all carved-out drugs processed through the FFS program. The Board had no questions and there was no discussion.

- Quarterly Evaluation Report: 4Q2021 (October 2021 – December 2021) – Ms. Fingado presented a summary of the evaluation report published in the 4th quarter of 2021, which covered the following two educational articles published during the 4th quarter of 2019:
  - Alert: New Global Guidelines for the Treatment of Asthma – October 2019
  - Improving the Quality of Care: Risks Associated with Use of Gabapentin – December 2019

  Ms. Fingado showed that since the original article was published in October 2019, there have continued to be annual updates to the GINA Report. Ms. Fingado stated that the 2021 GINA Report includes guidance on implications of

COVID-19 infection on asthma management and recommends the following two tracks for adults, based on evidence about outcomes:

- Track 1: Low-dose ICS/formoterol is the preferred reliever medication and daily maintenance medication
- Track 2 (if Track 1 not possible or preferred by patient): Recommend use of low-dose ICS whenever a SABA is used as a reliever treatment and ICS for daily maintenance

Ms. Fingado recommended the Board continue with an annual review of the GINA report and perform regular evaluations of asthma performance measures using pharmacy and medical claims data in the Medi-Cal population.

Ms. Fingado also reported on the use of gabapentin in the Medi-Cal population since the publication of the original article, which was published in December 2019.

Ms. Fingado reported that the results from the evaluation show the total number of beneficiaries with at least one paid claim for gabapentin during the measurement year have increased by 13.4% in two years, compared with an overall increase in the eligible Medi-Cal population of 7.5% during this same time. However, Ms. Fingado noted promising trends that show an 11.5% decrease in the percentage of continuously eligible FFS beneficiaries with concomitant use of gabapentin and any opioid medication, and a 2.7% decrease in the percentage of continuously eligible FFS beneficiaries with concomitant use of gabapentin, any opioid medication, and two additional CNS depressants. Ms. Fingado suggested that these data, in combination with data showing a 2.5% decrease in the percentage of continuously eligible FFS beneficiaries with an FDA-approved indication for gabapentin, indicate that gabapentin may be increasingly used off-label as a substitute for opioid pain medication instead of being prescribed concomitantly with opioid pain medication. Ms. Fingado noted that overall utilization of both gabapentin and pregabalin continues to increase without a corresponding increase in any conditions in which gabapentinoids are FDA-approved to treat. Ms. Fingado noted that pregabalin was added to the Medi-Cal List of Contract drugs on September 1, 2020, and a review of pharmacy claims data found that the total number of paid claims for both pregabalin and gabapentin through October 31, 2021, exceeded the total number of paid claims for all of 2020. Ms. Fingado recommended that the Board continue to monitor CNS polypharmacy and provide updates to the Board, as needed on utilization.

Dr. Leung asked if there are plans to evaluate the use of formoterol combination inhalers vs albuterol, including the change in use from before and after the GINA guidelines. Dr. Leung suggested we could use the asthma medication ratio (AMR) to evaluate outcomes after the GINA mailing. Ms. Fingado reviewed the proposed calendar for future retrospective DUR topics, which includes an evaluation of selected adult and child core set measures at each Board meeting. Ms. Fingado noted that a review of the AMR measure for both adults and children would be on the agenda for the May meeting. With the proposed schedule, Ms. Fingado reported that all pharmacy-related core set measures would be assessed and presented to the Board at least once per year.

d. Looking Ahead: Ms. Chan called for any future meeting agenda topics to be sent to DHCS. Ms. Chan noted that Alameda Alliance for Health is scheduled for presentation at the May meeting. Dr. Nakahiro asked via the webinar chat feature if the deadlines for this year's annual report to CMS would be the same as last year. Ms. Chan responded that if the final survey is provided from CMS by April 1, the deadlines for MCOs to complete their survey would remain the same as last year. Ms. Chan noted the reporting dates for the FFY 2021 survey do not yet include any overlap with Medi-Cal Rx.

6) PUBLIC COMMENTS	• There were no public comments.
7) CONSENT AGENDA	• The next Board meeting will be held on May 17, 2022, location pending.
8) ADJOURNMENT	• The meeting was adjourned at 12:23 pm.

Action Items	**Ownership**
Incorporate edits from Dr. Wong into the November 16, 2021, Board meeting minutes and post to the DUR website.	Amanda
The DUR Board recommendation to modify the Board goals for 2022 to include monitoring the effectiveness of the MTM program for chronic conditions will be submitted to DHCS.	Board/DHCS
The DUR Board recommendation to expand the description of the Vital Directions framework to include the four essential infrastructure needs will be submitted to DHCS.	Board/DHCS

Old Business

Action Items from February 15, 2022:

- The Board recommends modifying the 2022 Board goals to include monitoring the effectiveness of the MTM program.
  - Dr. Wofford will continue to provide the Board with regular updates on the MTM program

- The Board recommends expanding the description of the Vital Directions framework to include the four essential infrastructure needs.
  - On agenda for discussion today, along with the updated Vital Directions framework published in 2021

Medi-Cal DUR

Updated Global Medi-Cal DUR Board 2022 Goals

Yana Paulson, PharmD
Chair, Global Medi-Cal DUR Board
May 17, 2022

2022 Board Goals - 1

- Advise DHCS on updates/additions to existing Drug Utilization Review reports through Medi-Cal Rx
  - Collaborate with Magellan to explore new system capabilities
  - Focus on medication safety and effective use
- Continue to promote dialogue and collaboration with MCOs
  - Present innovative practices and projects
  - Share lessons learned
  - Disseminate DUR Educational Bulletins and Outreach Letters
  - Integrate/align DUR Actions
- Conduct DUR activities after full implementation of the State Plan Amendment (SPA) for the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

2022 Board Goals - 2

- Continue to focus on the top three DUR priority areas established in 2018-2019, *using the new capabilities available once Medi-Cal Rx is implemented*
  - Optimizing drug prescribing and dispensing, including specialty drugs.
  - Optimizing medication management, prevention, and wellness for chronic conditions, with a special focus on diabetes, hypertension, depression, and anxiety
  - Optimizing pain management and use of opioids

2022 Board Goals - 3

- Continue to use "Vital Directions" framework as a guide, including the include four infrastructure needs:
  - Measure what matters most
  - Modernize skills
  - Accelerate real-world evidence
  - Advance science

2022 Board Goals - 4

- Continue to engage with DHCS on programs related to DUR activities, including the following:
  - California Advancing and Innovating Medi-Cal (CalAIM)
  - DHCS Comprehensive Quality Strategy
  - Medication Therapy Management Services
    - Support and promote MTM to achieve > 90% adherence for specialty medications
    - Identify barriers to the provision of MTM services
    - Monitor the effectiveness of the MTM program

Questions?

GLOBAL MEDI-CAL DRUG USE REVIEW BOARD
FEBRUARY 15, 2022 BOARD MEETING MCP ACTIONS

MCP: _____

Name of DUR representative: _____Attended meeting? Yes ___ No ___

Reminders

- MCPs are required to ensure representation and participation at Global Medi-Cal DUR Board meetings, either in-person or via webinar. Refer to the Global Medi-Cal DUR Board bylaws for the attendance requirements for Global Medi-Cal DUR Board members
- MCPs are required to have a process for distribution of provider education programs and materials developed by Global Medi-Cal DUR Board to their providers

Summary of Required Actions

I. Educational Bulletins: MCP to have a process for distribution of provider education programs and materials developed by Global DUR Board to their providers via established mechanisms.

Required dissemination of DUR educational bulletins and alerts		
Description	**Mechanism of Dissemination**	**Date of Dissemination**
Bulletin (December 2021): Improving the Quality of Care: Legislative Impact on the Use of Naloxone		

Summary of Global Medi-Cal DUR Board Activities
(not required to document on the Annual Report to CMS)

1. **Review 2021 Board accomplishments.**

   Actions:
   b. Review at MCP's P&T/DUR Committee.
   c. Share individual MCP's success with DUR Board at future meetings.

2. **Review Board goals and priorities for 2022.**

   Actions:
   a. Review Board goals and priority areas at MCP's P&T/DUR Committee.
   b. Consider presenting best practices on a priority area and share lessons learned at an upcoming Global Medi-Cal DUR Board meeting.

3. **Review list of approved topics for retrospective DUR reviews, educational articles, and educational outreach.**

   Actions:
   a. Discuss and prioritize topics at MCP's P&T/DUR Committee.
   b. Consider sharing information at the next Board meeting.

4. **Review Board Actions and Recommendations from the February 15, 2022, DUR Board Meeting (see "Action Items" found in the last section of the meeting minutes).**

   Actions:
   a. Discuss the actions and recommendations at the MCP's P&T/DUR meeting.
   b. Consider offering feedback at a future Board meeting.

5. **Prepare CMS Managed Care Organization (MCO) Drug Utilization Review annual survey.**

   Actions:
   a. Review the FFY 2021 CMS Drug Utilization Review annual survey questions, complete the fillable survey, and submit via email to PBDClinicalOps@dhcs.ca.gov by June 1, 2022.

DHCS Update

Pharmacy Benefits Division
May 17, 2022

Topics for Discussion

- Medication Therapy Management (MTM) Program
- Medi-Cal Rx

Vital Directions Framework

Discussion
Global Medi-Cal DUR Board
May 17, 2022

"Vital Directions" Framework

- DUR board uses "Vital Directions" developed by the National Academy of Medicine (NAM) as a guide.
- The 2017 "Vital Directions" include four infrastructure needs:
  - Measure what matters most
  - Modernize skills
  - Accelerate real-world evidence
  - Advance science
- The DUR board in November 2018, further modified the infrastructure needs to include:
  - Measure what matters most
  - Use clinical guidelines
  - Academic Detailing

"Vital Directions" Framework -2

- "Vital Directions" framework updated in 2021 to include:
  - Reduce health disparities and inequities in the most vulnerable and underserved populations by improving health access.
  - Increase resources to enhance collaboration with public health agencies and the community to prevent infectious disease spread.

Questions?

Medi-Cal DUR

JAMA | Special Communication

Vital Directions for Health and Health Care
Priorities From a National Academy of Medicine Initiative

Victor J. Dzau, MD; Mark B. McClellan, MD, PhD; J. Michael McGinnis, MD, MPP; Sheila P. Burke, MPA, RN; Molly J. Coye, MD, MPH; Angela Diaz, MD, MPH; Thomas A. Daschle, BA; William H. Frist, MD; Martha Gaines, JD, LLM; Margaret A. Hamburg, MD; Jane E. Henney, MD; Shiriki Kumanyika, PhD, MPH; Michael O. Leavitt, BA; Ruth M. Parker, MD; Lewis G. Sandy, MD; Leonard D. Schaeffer, BA; Glenn D. Steele Jr, MD, PhD; Pamela Thompson, MS, RN; Elias Zerhouni, MD

IMPORTANCE Recent discussion has focused on questions related to the repeal and replacement of portions of the Affordable Care Act (ACA). However, issues central to the future of health and health care in the United States transcend the ACA provisions receiving the greatest attention. Initiatives directed to certain strategic and infrastructure priorities are vital to achieve better health at lower cost.

OBJECTIVES To review the most salient health challenges and opportunities facing the United States, to identify practical and achievable priorities essential to health progress, and to present policy initiatives critical to the nation's health and fiscal integrity.

EVIDENCE REVIEW Qualitative synthesis of 19 National Academy of Medicine–commissioned white papers, with supplemental review and analysis of publicly available data and published research findings.

FINDINGS The US health system faces major challenges. Health care costs remain high at $3.2 trillion spent annually, of which an estimated 30% is related to waste, inefficiencies, and excessive prices; health disparities are persistent and worsening; and the health and financial burdens of chronic illness and disability are straining families and communities. Concurrently, promising opportunities and knowledge to achieve change exist. Across the 19 discussion papers examined, 8 crosscutting policy directions were identified as vital to the nation's health and fiscal future, including 4 action priorities and 4 essential infrastructure needs. The action priorities—pay for value, empower people, activate communities, and connect care—recurred across the articles as direct and strategic opportunities to advance a more efficient, equitable, and patient- and community-focused health system. The essential infrastructure needs—measure what matters most, modernize skills, accelerate real-world evidence, and advance science—were the most commonly cited foundational elements to ensure progress.

CONCLUSIONS AND RELEVANCE The action priorities and essential infrastructure needs represent major opportunities to improve health outcomes and increase efficiency and value in the health system. As the new US administration and Congress chart the future of health and health care for the United States, and as health leaders across the country contemplate future directions for their programs and initiatives, their leadership and strategic investment in these priorities will be essential for achieving significant progress.

Editorial

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Victor J. Dzau, MD, National Academy of Medicine, 500 Fifth St NW, Washington, DC 20001 (vdzau@nas.edu).

JAMA. doi:10.1001/jama.2017.1964
Published online March 21, 2017.

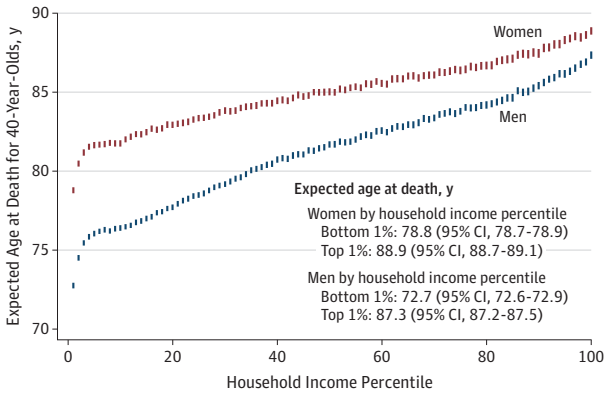
The US health and health care system is at a critical juncture. Discussions about repeal of the Affordable Care Act (ACA) introduce considerable uncertainty into the health care marketplace and for the 20 million people newly insured during the past 6 years,[1] but the range of health and health care challenges spans far beyond the coverage provisions of the ACA. Unparalleled health costs, structural inefficiencies, fragmented care delivery, payment hardships, and proliferating administrative requirements impose burdens on individuals, clinicians, employers, and entire communities. The consequences are especially severe for those who are ill, lack needed medical and social services, and have lower incomes, as indicated by the association of lower incomes with substantially lower life expectancies (**Figure 1**). But inadequate and inappropriate treatment, overdiagnosis and underdiagnosis, medical errors, and excessive costs are also experienced by many other individuals in the United States.

These serious systemwide challenges are complicated by increases in illness and disability from an aging population, emerging infectious diseases, and physical, behavioral, and mental health disorders such as opioid abuse, tobacco use, obesity, depression, and their related chronic diseases. Although US residents with higher incomes have never been healthier, conditions such as these are life-altering threats for many individuals. The most recent data on US life expectancy indicate not only sustained health disparities by income level and by race/ethnicity, but also a decline in overall life expectancy for the first time in nearly 2 decades.[3]

At the same time, compelling opportunities and novel tools are emerging to possibly solve these problems. Insights now underscore the central importance of social, behavioral, and environmental factors for people's health throughout the life span. Technology is reshaping every dimension of health care, from the ability to treat organ system failure and the capacity to visualize metabolic processes in real time to the use of digital systems that can record, inform, connect, and assess care experiences, introducing new possibilities for precision medicine, the creation of evidence, and the delivery of care.[4] Scientific discoveries offer breakthrough potential for greater precision in the prevention, detection, and treatments of illness and disease.

The nation's challenge is to choose priorities and actionable steps to address them that will have the greatest effect in improving the health of the population. Moreover, as indicated in **Figure 2**, it is not only the nation's health but its fiscal capacity that is at risk, as health care spending reduces investments in education, infrastructure, and other arenas important to the daily lives of US residents. In 1974, the United States spent $14.8 billion on major health care programs, $55 billion on Social Security, and an estimated $199.6 billion on all other spending; by 2015, this had changed to $936.5 billion, $881.9 billion, and $1869.9 billion, respectively (note that major health care programs include spending for Medicare [net of premiums and other offsetting receipts], Medicaid, and the Children's Health Insurance Program as well as spending to subsidize health insurance and to stabilize premiums for health insurance purchased by individuals and small employers). The $3.2 trillion spent annually for health care in the United States[6] is far higher than anywhere else in the world,[7] and the magnitude of the nation's excessive expenditures was estimated in 2009 at approximately 30% of health care costs[8] and in 2012 at between 21% and 47%[9]—including unnecessary services, delivery inefficiencies, excess administrative costs, high prices, missed prevention opportunities, and fraud—underscoring the need for better use of resources. Because this trajectory of health care spending is unsustainable, reforms are needed that enable health care organizations, communities, and individuals to redirect resources to uses that achieve better health, promote efficiency, and reduce waste. Given that the leading health determinants are outside of health care,[10] policies must not only encourage more judicious use of health care services, but also ensure supports

Figure 1. Race- and Ethnicity-Adjusted Life Expectancy for 40-Year-Olds by Household Income Percentile, 2001-2014

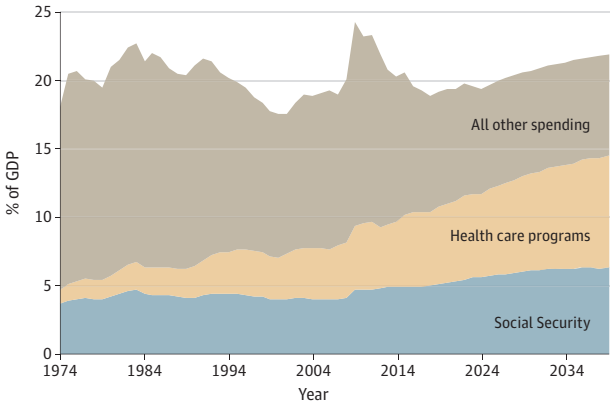


Mean household income in thousands, $[a]					
Women	24	45	71	112	1.9 million
Men	26	50	77	119	2.0 million

Higher income is associated with longer life expectancy across the income distribution. The vertical height of each bar depicts the 95% confidence interval. The difference between expected age at death in the top and bottom income percentiles is 10.1 years (95% CI, 9.9-10.3 years) for women and 14.6 years (95% CI, 14.4-14.8 years) for men. To control for differences in life expectancies across racial and ethnic groups, race and ethnicity adjustments were calculated using data from the National Longitudinal Mortality Survey and estimates were reweighted so that each income percentile bin has the same fraction of black, Hispanic, and Asian adults. Reprinted from *JAMA*.[2]

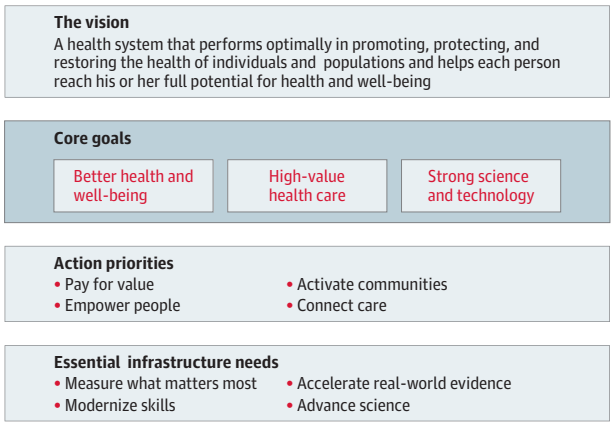
[a] Averaged across years and ages. The data are in thousands unless otherwise indicated.

Figure 2. Historical (1974-2015) and Projected (2016-2039) Federal Spending on Health Care and Other Programs



All other spending includes other mandatory spending and discretionary spending (including defense and nondefense). Data are from the Congressional Budget Office.[5] GDP indicates gross domestic product.

Figure 3. Vital Directions Framework



Achieving the vision of the Vital Directions for Health and Health Care requires focusing on 3 core goals—better health and well-being, high-value health care, and strong science and technology—and pursuing the action priorities and infrastructure needs required for their achievement.

for better health behavior and facilitate integration of health-related social service interventions.[2] Furthermore, by fostering incentives and culture change supportive of proven, value-based models of care payment and delivery as well as connected health care and information, greater efficiency, better results, and more person-engaged care could be achieved.[11]

As the new administration and Congress work to craft the future of US health and health care, this Special Communication is offered by members of a steering committee of experienced nonpartisan experts and opinion leaders assembled by the National Academy of Medicine (NAM). In the spirit of the chartered mandate and long-standing service of the National Academies to provide trusted, independent counsel to the nation, the NAM last year launched an initiative to consider practical and achievable priorities essential to the nation's health and fiscal integrity. Underscoring the importance of the issues, this initiative is named Vital Directions for Health and Health Care.

The Priorities

The Vital Directions initiative is motivated by the vision of a health system that performs optimally in promoting, protecting, and restoring the health of individuals and populations and helps each person reach her or his full potential for health and well-being (**Figure 3**). Attainment of this vision requires focusing on 3 core goals—better health and well-being, high-value health care, and strong science and technology—and, in turn, pursuing the action priorities and infrastructure needs required for their achievement (**Box 1**).

Across the 3 goals of the Vital Directions for Health and Health Care initiative—better health and well-being, high-value health care, and strong science and technology—the Vital Directions Steering Committee identified 19 issue areas to be assessed in expert-written articles. The National Academy of Medicine convened more than 150 of the nation's leading health and policy experts to author the 19 articles, each of which addressed pressing policy challenges and opportunities and offered specific recommendations for achieving progress (**Box 2**). Summarized in this Special Communication are the most potentially transformative crosscutting policy directions identified from those assessments, indicated as action priorities and infrastructure needs essential to addressing these priorities. These strategies and priorities are offered to assist the new administration and others leading change throughout health and health care at national, state, local, and institutional levels. Pursuing these action priorities and essential infrastructure needs as part of major 2017 legislative and executive initiatives can achieve better health and lower costs.

Action Priorities

From across the spectrum of the 19 discussion papers developed through the Vital Directions initiative, 4 crosscutting action priorities emerged: pay for value, empower people, activate communities, and connect care. Whether from the perspective of the need to prevent and control heart disease, cancer, or diabetes; to prevent, identify, and treat people with problems of mental health and addiction; or to streamline and improve access to the range of services needed, these 4 action priorities are vital to progress. Moreover, because these priorities represent a substantial departure from current patterns of health and health care services, their advancement requires strong leadership, commitment, and strategic emphasis.

Pay for Value—Deliver Better Health and Better Results for All

Leaders throughout the United States adhere to the principle that no individual should lack access to basic health services. Central to the realization of this principle is ensuring that those services deliver the greatest possible value and minimize waste. But the nation falls substantially short of that aim. Although contributions vary across population groups, shortfalls in medical treatment have a relatively small effect on the occurrence of early deaths throughout the population—accounting for only about an estimated 10% of

Box 1. Vital Directions for Health and Health Care: The Priorities

Action Priorities

Pay for value—deliver better health and better results for all

Empower people—democratize action for health

Activate communities—collaborate to mobilize resources for health progress

Connect care—implement seamless digital interfaces for best care

Essential Infrastructure Needs

Measure what matters most—use consistent core metrics to sharpen focus and performance

Modernize skills—train the workforce for 21st-century health care and biomedical science

Accelerate real-world evidence—derive evidence from each care experience

Advance science—forge innovation-ready clinical research processes and partnerships

Box 2. Vital Directions for Health and Health Care: Issue Areas

Better Health and Well-being

Systems strategies for better health throughout the life course

Addressing social determinants of health and health disparities

Preparing for better health and health care for an aging population

Chronic disease prevention: tobacco, physical activity, and nutrition for a healthy start

Improving access to effective care for people who have mental health and substance use disorders

Advancing the health of communities and populations

High-Value Health Care

Benefit design to promote effective, efficient, and affordable care

Payment reform for better value and medical innovation

Competencies and tools to shift payments from volume to value

Tailoring complex care management, coordination, and integration for high-need, high-cost patients

Realizing the full potential of precision medicine in health and health care

Fostering transparency in outcomes, quality, safety, and costs

The democratization of health care

Workforce for 21st-century health and health care

Strong Science and Technology

Information technology interoperability and use for better care and evidence

Data acquisition, curation, and use for a continuously learning health system

Innovation in development, regulatory review, and use of clinical advances

Targeted research: brain disorders as an example

Training the workforce for 21st-century science

premature deaths overall—while behavioral patterns, genetic predispositions, social circumstances, and environmental exposures have been estimated to account for approximately 40%, 30%, 15%, and 5% of premature deaths, respectively.[12] Yet the majority of health expenditures are devoted exclusively to treatment. Because payments have not been explicitly linked to the value of the services or evidence of their necessity, per-person health expenditures in the United States are much higher than in other high-income countries.[7]

To advance value-based care for all, policy reforms should do the following:

- **Drive health care payment innovation providing incentives for outcomes and value.** Payment for individual services inherently encourages volume over outcomes. The reward focus adopted by all payers needs to target patient- and population-specific profiles that yield better outcomes at reasonable costs for care for a designated population over a specified period.[13]
- **Help clinicians develop the core competencies required for new payment models.** As new payment models are implemented and tested for their effects on care outcomes and value as well as patient and clinician satisfaction, clinician practices need to develop the adaptive core competencies to succeed.
- **Remove barriers to integration of social services with medical services.** Treatments are frequently prescribed without consideration of the social, behavioral, and environmental factors that are important determinants of health.[14] Integrated arrangement, financing, and delivery of nonmedical social services (eg, food, housing, transportation, and income assistance) with medical services is important to improve outcomes, yield savings, and enhance equity.[15] Integration of this sort could be achieved through virtual integration models such as Medicaid health homes, which use a team-based clinical care approach while connecting care to community resources and supports.[16]

The following are example policy initiatives from the Vital Directions discussion papers:

- Sustain and accelerate the implementation, demonstration, and assessment of alternative payment models supported by public and private health care payers to reward value and improve outcomes and health.
- Reward measurement streamlining that helps identify and reward innovation and outcomes delivering value at systemwide and population levels (population-based payments).
- Support public-private collaborations among industry and government, for example, the Accountable Care Learning Collaborative, which helps clinicians and other health care delivery groups and organizations develop competencies needed for success in the use of alternative payment models.[17]
- Implement successful models for health and social services integration, for example, funding stream integration so that Medicaid managed care plans can coordinate with social and community interventions proven effective in improving outcomes and reducing costs.

Empower People—Democratize Action for Health

Consistently and effectively engaging patients and families is essential to improve health outcomes and efficient use of care. Yet care and care instructions are still too often poorly matched to the personal context of patients' daily lives or their individual goals.[18] Health care must not only be safe and effective, but also be understandable and practical, accounting for patient and family knowledge and

circumstances and linking them with easy access to ongoing information and communication channels. Furthermore, individuals' health data are increasingly siloed and are often in electronic health records that may be impossible to access when needed. Beyond the need for a platform to integrate health data is the need for practical assurance to patients of ownership of their own data, which in most cases are now held by physicians and hospitals.[19]

To empower people, policy reforms should do the following:

- **Link care and personal context.** Clinicians should work together with patients and their families to ensure that care provided matches closely with each individual's goals.
- **Communicate in a way appropriate to literacy.** To foster trust and active patient engagement, policy makers and health leaders should focus on making information more available, understandable, and useful for all. Improving health literacy also stands to have significant economic benefit; low health literacy has been estimated to cost the United States $106 billion to $238 billion annually.[20]
- **Promote effective telehealth tools.** Telehealth technologies—use of internet, telephone, and other methods—have shown some promise in increasing patient access to medical care, particularly in remote or underserved areas, and reducing costs.[21,22] Harmonizing state-specific physician licensure rules and restrictions as well as reimbursement eligibility requirements would help promote their scalability and broader use.
- **Ensure patient data access, ownership, and privacy.** Empowering patients through ownership and protection of their health data would allow patients the opportunity to use, act on, and derive the most (personal) value from their health information.[23] Data ownership combined with better assurance of data privacy and security would increase the likelihood that patients would be willing to share their health information.

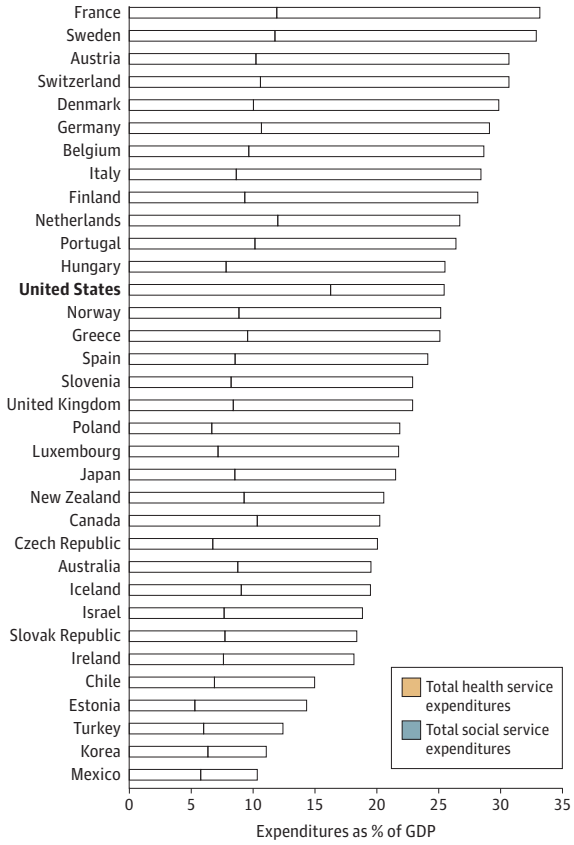
The following are example policy initiatives from the Vital Directions discussion papers:

- Promote development of clinical practice guidelines and decision support tools to encourage physicians to engage with each patient on their personal context and goals in making care decisions.
- Support patient communication research on and decision-making strategies to determine the most effective approaches to relaying information on care, cost, and quality, such as the Patient-Centered Outcomes Research Institute (PCORI) Communication and Dissemination Research program focusing on approaches to communicate and disseminate health information and research findings to patients.[24]
- Establish harmonized licensure and reimbursement for telehealth clinicians, so that telehealth clinicians may provide services across state lines.

Activate Communities—Collaborate to Mobilize Resources for Health Progress

Health begins in communities, where people live, work, and play. However, as the nation experiences increasing health disparities, the gap in life spans between the rich and the poor has increased[2] and discrepancies between urban and rural health care access and quality persist.[25] In 2015, aggregate population-wide life expectancy experienced a concerning decline. Whether this will continue is unclear. Health disparities are not inevitable; they are a product not only of health care access and quality, but also of community-based social, economic, and environmental conditions that can be changed. Work sponsored by the NAM Culture of Health program assessed the health-related effect from targeting social determinants in 9 communities and found that, altogether, multisectoral community-wide leadership can be effective in reducing the adverse effects of key social determinants on health disparities.[26] Moreover, the United States invests far less than peer nations on community-based social services (**Figure 4**) that are important to health outcomes. Community-wide leadership and capacity are essential not only to reducing disparities, but also to combating the nation's most pressing and costly health threats—such as chronic disease and multiple comorbidities—by promoting healthy environments and behaviors and ensuring that the necessary supports are in place to achieve health improvement.

Figure 4. Health Care and Social Service Spending Across Countries in the Organisation for Economic Co-operation and Development (OECD)

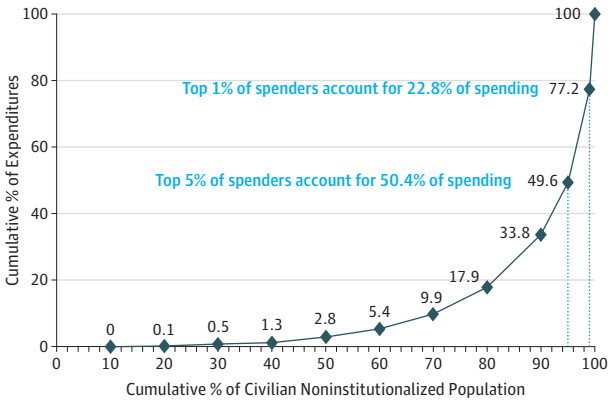


Compared with other high-income countries, the United States spends a greater proportion of health care and social service expenditures on health care services. For every $1 spent on health care, about $2 is spent on social services by countries in the OECD overall but only about $0.50 is spent on social services by the United States.[27] GDP indicates gross domestic product. Data are from OECD countries (n = 30) from 1995 to 2005 according to the 2009 release of the OECD Health Data 2009 Statistics and Indicators and OECD Social Expenditure Database. Adapted from Bradley and Taylor.[27]

To activate communities, policy reforms should do the following:

- **Invest in local leadership and infrastructure capacity for public health initiatives.** Transformative change in health and health care requires maintaining and strengthening the capacity to deliver essential public health services, including ongoing collaboration with business, education, housing, and transportation stakeholders.

Figure 5. Distribution of Personal Health Care Spending in the US Civilian Noninstitutionalized Population, 2014



In 2014, the top 1% of health care spenders accounted for 22.8% of total health care spending and the top 5% of health care spenders accounted for 50.4% of total health care spending. Data are from the Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality.[28]

- **Expand community-based strategies targeting high-need individuals.** High-need patients, often characterized as those with multiple comorbidities, disproportionately drive health care costs, with the top 1% and 5% of spenders accounting for 22.8% and 50.4% of health care spending, respectively (**Figure 5**).[28] The right care for these patients requires close alignment and coordination of medical and social services. Community care (health) teams, typically associated with patient-centered medical homes, can help coordinate these services for complex patients, but they strongly rely on community-based organizations to provide the social supports and services needed (eg, food, housing, income, and care assistance).[29]
- **Provide strong state-based capacity for guidance, assistance, and synergy for local health efforts.** Success in achieving better health at lower cost will depend on strategies implemented at the local level. Resources, flexibility, and insights from successful state innovation models and model Medicaid waivers that encourage and empower local leaders can provide guidance for customizing and scaling community health innovations.

The following are example policy initiatives from the Vital Directions discussion papers:

- Require that tax-exempt health organizations meeting Internal Revenue Service requirements for community benefit work through coordinated community-wide public-private partnerships and multisectoral initiatives.
- Support states' flexible use of grant funds for technical assistance to local leadership and collaborative action working to identify and mobilize action on the most important health challenges.
- Identify best practices from pilot programs from the Center for Medicare & Medicaid Innovation (CMMI) on approaches linking relevant health, education, social service, and legal system activities and resources to address individuals at highest risk and with the greatest needs.
- Give states flexibility to use Medicaid funds to implement best practices in targeting the most effective efforts for high-risk, vulnerable children (eg, prenatal to age 3 years) as well as adults at particular risk with complex, multifactorial conditions.

Connect Care—Implement Seamless Digital Interfaces for Best Care

Health care in the United States is complex and often difficult to navigate—for patients, families, and clinicians—but tools are available. The expanded adoption of health information technology has introduced powerful new opportunities for better health and health care,[30] including the potential for greater accountability and value, enhanced public engagement, improved public health surveillance, and more rapid development and distribution of new therapies. Yet important challenges remain. System incompatibilities and clinician discomfort levels need to be overcome. Clinical data do not consistently follow the patient to inform care across settings and over time. Aggregate clinical data are not available to inform health policy, generate discovery, or improve care efficiency and effectiveness.[31]

To achieve connected care, policy reforms should do the following:

- **Make necessary infrastructure and regulatory changes for clinical data accessibility and use.** The following barriers need to be removed: specifications for data developed but not adopted, commercially protective coding practices, proprietary data ownership and use restrictions, and misinterpretation of control requirements for use of clinical data as a resource for new knowledge. The recently passed 21st Century Cures Act contains provisions to encourage sharing and use of clinical data, but those provisions require local action.
- **Create principles and standards for end-to-end interoperability.** Specific standards are needed for end-to-end (system, clinician, and individual) interoperability. Despite the rapidly progressing technical capacity of digital technology for health, interoperability between and among systems is very limited, leading to serious clinical and administrative inefficiencies and inhibiting more responsive and effective care.[32]
- **Identify information technology and data strategies that support continuous learning.** The technical capacity now exists for continuous communication and learning throughout health care—among organizations, between clinicians, between devices, and between patients and care partners. Comprehensive strategy and action are required to improve data infrastructure, foster public trust around data privacy and security, and resolve inconsistent state and local policies on data use and sharing.

The following are example policy initiatives from the Vital Directions discussion papers:

- Use US Department of Health and Human Services (HHS) regulatory and reimbursement mechanisms to enforce existing standards for interoperability across electronic health records and medical devices.
- Through the HHS, sponsor a public-private standards organization to commission the necessary additional standards, for example, open, standardized application programming interfaces to support continuously improving standardized service-oriented architecture for interoperability and clinical decision support.
- Streamline inconsistent state and local security and privacy policies related to data exchange and use, such as federal guidelines enabling states and localities to harmonize data use policies and reciprocal support agreements.
- Building on the principle of patient ownership of data, foster active patient access and use of their own data for care and evidence improvement.

Essential Infrastructure Needs

To achieve the 4 action priorities, there must be commitment to essential infrastructure needs common across the 19 Vital Directions discussion papers: measure what matters most, modernize skills, accelerate real-world evidence, and advance science. The foundation for progress in any of those 19 areas resides in the availability of accurate information on the central determinants of progress, the skills to address those determinants, the pace at which new approaches can be developed, and the knowledge and tools available to better understand, assess, and improve those approaches.

Measure What Matters Most—Use Consistent Core Metrics to Sharpen Focus and Performance

Measurement is essential to guide progress. Ironically, as measurement tools and skills have advanced, the proliferation of reporting requirements has resulted in clinical measures now numbering in the thousands, raising serious concerns about the time, cost, validity, generalizability, and overall clinician and financial burden of clinical measurement. Results become meaningless if measures are unreliable and inconsistent.

To achieve meaningful measurement, policy reforms should do the following:

- **Focus reliably and consistently on factors most important to better health and health care.** To reduce the burden and increase the utility of measurement, an anchor set of core measures standardized and available consistently over time at national, state, local, and institutional levels can provide baseline reference points and improve the reliability of broader measurement, evaluation, accountability, and research efforts. The National Academies report *Vital Signs: Core Metrics for Health and Health Care Progress*[33] provides a framework for 15 such measures of health, care quality, value, and engagement.
- **Create the national capacity for identifying, standardizing, implementing, and revising core measures.** The *Vital Signs* committee recommended that the Secretary of Health and Human Services identify a lead organization for each of the 15 core measures and, in turn, engage related stakeholder organizations in the refinement process. The committee also recommended creation of an ongoing, independent capacity to steward the revision process over the longer term.
- **Invest in the science of performance measurement.** With the increasing capacity and importance of performance measurement, an ongoing investment is needed for continuous assessment of measures application, proposing and testing improved approaches, and periodic updating of individual measures, their components, and the measure set.[34]

The following are example policy initiatives from the Vital Directions discussion papers:

- Initiate an HHS process to refine and implement the *Vital Signs* core measures nationally, beginning with the federal categorical and health care funding programs, including a variation to be used by states in return for Medicaid management flexibility.
- Provide waivers from Medicare reporting requirements for health care organizations working in multiorganization collaborations to implement and report on core systemwide performance measures.
- Explore the design of an independent, standards-setting body for reports on health care performance measures, possibly modeled after the Financial Accounting Standards Board, which establishes financial accounting and reporting standards for companies and nonprofit organizations.[35]
- Establish a multiagency collaborative research initiative on the science of performance measurement, including how best to develop, test, evaluate, and improve measures.

Modernize Skills—Train the Workforce for 21st-Century Health Care and Biomedical Science

Investing in and strengthening the capacity of the health care and biomedical science workforces is critical to ensuring the health, economic, and physical security of the United States as well as global leadership in research and innovation. This investment must take new directions. The health care workforce of the 21st century must be adept at managing increasingly complex patients and populations, particularly as people live longer and the burden of chronic disease continues to increase, the complexity of medicine increases, and the research tools become more sophisticated. Ensuring a 21st-century biomedical science workforce will require modern education and training approaches; existing pathways are becoming outdated and fragmented[36] and no longer guarantee stable, successful careers.

To modernize the skills of the health care and biomedical science workforce, policy reforms should do the following:

- **Reform health care training to meet the nation's changing health needs and opportunities.** Reorienting training and practice to coordinated team-based approaches is essential to care delivery in today's increasingly complex care environment. This can be done by fostering the skills to work collaboratively in interdisciplinary teams and keep pace with technology advances.[37]
- **Create new education and training pathways for the science workforce.** The science workforce of the future will need to be diverse, multidisciplinary, team oriented, and adept at data analytics and informatics. Attracting and retaining the most talented individuals will require innovative education pathways and programs to create and support a cutting-edge, cross-disciplinary health science workforce.

The following are example policy initiatives from the Vital Directions discussion papers:

- Engage the scientific community, private foundations, state higher education officials, and federal health professions funders in proposing a public-private national initiative on health professions education that is team based, collaborative, multidisciplinary, and skilled in health information technology and informatics.
- Require that organizations delivering care as Medicare alternative payment models have the clinical research, information technology, and systems engineering personnel for continuous learning and improvement.
- Implement a prominent initiative to attract the most talented people to shape and lead the new biomedical research enterprise, a sort of NextGen Opportunity Fund.[38]

Accelerate Real-World Evidence—Derive Evidence From Each Care Experience

The potential to analyze large amounts of health-related data from actual patient care holds immense promise for improving medical

care by better informing care decisions, increasing drug and medical device safety, more accurately evaluating treatment effectiveness, and accelerating scientific discovery.[39] However, progress has been hampered by technical, regulatory, and cultural barriers, including an outdated clinical research model, an inadequate data-sharing incentive structure, and gaps in methods appropriately suited for such data. Randomized clinical trials, while still the gold standard of clinical research, are very expensive and can be limited in their generalizability and ability to reflect results in clinical practice.[40] The prospects now exist for a health system that is constantly learning, adjusting, and improving, and elements of the recently enacted 21st Century Cures Act provide impetus to this work.

To accelerate reliable evidence, policy reforms should do the following:

- **Advance continuously learning clinical research drawing on real-world evidence.** Complementing randomized clinical trials, the ability to collect data from actual clinical practice presents a great opportunity to gain new insights about the efficacy and safety of new drugs and medical devices as well as the relative effectiveness and efficiency of those in use. The National Institutes of Health (NIH), the US Food and Drug Administration (FDA), and other leading research agencies are actively developing strategies in this respect.
- **Foster a culture of data sharing by strengthening incentives and standards.** As with routine clinical data, research participants have presumptive rights to access and share their own health data. Researchers have a responsibility to accept that strong science and good scientific citizenship require individual-level data to be more accessible for evaluation and reuse, with appropriate safeguards.[41]
- **Partner with patients and families to support evidence generation and sharing.** Partnering with patients—and in the process, better ensuring their privacy and improving trust—is a linchpin for effective evidence generation and data sharing for care improvement and learning. Patient engagement throughout the research process can help identify unmet needs and future research priorities as well as improve clinical outcomes.[42]

The following are example policy initiatives from the Vital Directions discussion papers:

- Create public-private partnerships to build on existing pilot studies to assess and expand real-world evidence development in both preapproval and postapproval settings.
- Provide incentives for data sharing, such as a reimbursement benefit for health systems that facilitate data access and sharing between patients and researchers.
- Implement initiatives to build patient skill sets for engagement, better define value in terms that reflect the patient perspective, and determine measures for trustworthiness and participation.

Advance Science—Forge Innovation-Ready Clinical Research Processes and Partnerships

Preeminence in science and technology has driven the nation's health and economic vitality. This requires national investment and unwavering support for science—basic and applied. However, cumbersome and outdated regulatory processes can make it difficult for the pharmaceutical industry to bring promising drugs and devices to market in a timely fashion. With US global investment in biomedical research softening,[43] maintaining leadership in science and innovation will require modernized and adaptive regulatory processes, research partnerships, and commercialization models.

To advance the pace of innovation, policy reforms should do the following:

- **Promote the conditions for scientific innovation.** Science needs investment. Important conditions for success include commitment to funding, support for basic and applied research, and acceleration in translation. Furthermore, taking advantage of data sets rapidly growing to very large sizes, new forms of science, technology, and evidence development can boost clinical care research. Opportunities include making greater use of evidence from actual clinical settings and of cognitive computing to better understand and ensure the most effective and appropriate interventions for the best possible clinical outcomes.
- **Support an adaptive and patient-driven regulatory framework.** Aligning discovery and development with current needs will require patient input and partnership in all stages of research and development; multidisciplinary teams; more efficient clinical trials with adaptive designs; and a blend of real-world and randomized clinical trial evidence.
- **Foster cross-disciplinary and public-private partnerships.** More collaboration among the government, academia, and industry scientists will be necessary to advance innovation, including in the most challenging therapeutic areas such as autoimmune, neurodegenerative, and inflammatory diseases.[44] Exploration of multifocal public-private research partnerships has been the focus of initiatives at the NIH and FDA, including those related to the programs expanding brain and cancer research. Pharmaceutical and device companies are exploring sharing trial data in the interest of advancing very-large-scale clinical databases to facilitate discovery.

The following are example policy initiatives from the Vital Directions discussion papers:

- Ensure research funding for basic and applied sciences.
- Create public-private programs to invest in and advance the science and related applications of big data analysis, such as cognitive computing.
- Facilitate patient support for evidence generation through expanded use of clinical data for discovery and real-time outcomes monitoring (eg, the FDA's National Medical Evidence Generation Collaborative, "EvGen"[45]).
- Implement precompetitive collaborations including industry, government, and academia to achieve needed breakthroughs in the most challenging therapeutic areas that cannot be done by any sector alone (eg, the Accelerating Medicines Partnership led by the NIH).

The Urgency

The opportunities described are real and substantial. As a nation, the United States has the world's largest observable discrepancy between the amount spent on health care and the health status of the population, but it also is positioned with the knowledge needed for improving value and outcomes. Greater involvement of people in their care processes, support for active community-wide initiatives, harnessing transformative connectivity of the digital infrastructure, and accelerating the movement toward a reward system based on results are all possible. Evidence exists on the potential of these priorities and on the steps necessary to deliver better health for all people in the United States at a sustainable cost. Furthermore, there are strong indications that these priorities will garner

broad support, with recent bipartisan legislation in some of these areas, such as the Medicare Access and CHIP Reauthorization Act (MACRA) for payment reform and the 21st Century Cures Act for more efficient drug development and approval.

The urgency is as compelling as the opportunities. Major concerns such as sustained, yet preventable, health disparities and perverse payment system incentives that drive unnecessary services and costs threaten achievement of possibilities for better health, greater equity, and even global economic competitiveness. Importantly, there is no easy fix or simple budgetary adjustment that will resolve excessive health care spending. As noted earlier, the excess costs stem from inefficiencies in multiple components of the health system, and their remediation will require a priori commitment to the priorities indicated. In fact, if even a relatively small portion of the approximately $1 trillion now spent unnecessarily on health care can be redirected to the high-priority investment opportunities described herein, the health and productivity benefits will ripple far beyond the health sector.

The complexity and magnitude of the issues as well as the promise for gain call for vigorous leadership from every quarter, including prominent federal initiatives as well as the state and local levels. At this vital inflection point in health and health care, the challenges are great, but so are the opportunities and knowledge to direct change. Prioritizing the nation's health through strong leadership and strategic investment is both possible and imperative for all Americans to reach their full potentials for health and well-being.

ARTICLE INFORMATION

Published Online: March 21, 2017. doi:10.1001/jama.2017.1964

Author Affiliations: National Academy of Medicine, Washington, DC (Dzau, McGinnis, Hamburg, Henney); Robert J. Margolis, MD, Center for Health Policy, Duke University, Washington, DC (McClellan); Malcolm Wiener Center for Social Policy, John F. Kennedy School of Government, Harvard University, Cambridge, Massachusetts (Burke); AVIA, Chicago, Illinois (Coye); Departments of Pediatrics and Preventive Medicine, Icahn School of Medicine at Mount Sinai, Mount Sinai Adolescent Health Center, New York, New York (Diaz); The Daschle Group, Washington, DC (Daschle); Owen Graduate School of Management, Vanderbilt University, Nashville, Tennessee (Frist); Center for Patient Partnerships, University of Wisconsin–Madison Law School (Gaines); Perelman School of Medicine, University of Pennsylvania, Philadelphia (Kumanyika); Leavitt Partners, Salt Lake City, Utah (Leavitt); Emory University School of Medicine, Atlanta, Georgia (Parker); UnitedHealth Group, Minnetonka, Minnesota (Sandy); University of Southern California, Los Angeles (Schaeffer); xG Health Solutions, Columbus, Maryland (Steele); American Organization of Nurse Executives, Chicago, Illinois (Thompson); Global Research and Development, Sanofi, Paris, France (Zerhouni).

Author Contributions: Drs Dzau and McGinnis had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Dzau, McClellan, McGinnis, Coye, Daschle, Frist, Gaines, Hamburg, Kumanyika, Leavitt, Parker, Sandy, Schaeffer, Steele, Thompson, Zerhouni.
Acquisition, analysis, or interpretation of data: McClellan, McGinnis, Burke, Diaz, Gaines, Henney.
Drafting of the manuscript: Dzau, McClellan, McGinnis, Burke, Daschle, Sandy, Steele.
Critical revision of the manuscript for important intellectual content: Dzau, McClellan, McGinnis, Coye, Diaz, Frist, Gaines, Hamburg, Henney, Kumanyika, Leavitt, Parker, Sandy, Schaeffer, Thompson, Zerhouni.
Statistical analysis: Diaz.
Obtained funding: Dzau, McGinnis.
Administrative, technical, or material support: McClellan, Coye, Diaz, Daschle, Hamburg.
Study supervision: Dzau, McGinnis, Diaz, Frist, Hamburg, Leavitt, Sandy, Steele.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr McClellan reported receiving personal fees from Johnson & Johnson. Dr Frist reported serving as a board member of Teladoc, MDSave, the Robert Wood Johnson Foundation, and the Kaiser Family Foundation; and being cofounder and board chairman of Aspire Health. Dr Henney reported serving as the home secretary of the National Academy of Medicine, member of the board of trustees for the China Medical Board, board member of The Commonwealth Foundation until 2016, member of the board of directors of Cigna Corp, lead director of the board for AmerisourceBergen Corp, and member of the board of directors of Cubist Pharmaceuticals (acquired by Merck in 2016). Mr Schaeffer reported serving on the board of directors of Walgreens Boots Alliance, a publicly held company that distributes to and operates prescription pharmacies. Dr Zerhouni reported serving as president of research and development for Sanofi. No other disclosures were reported.

Funding/Support: The National Academy of Medicine's Vital Directions for Health and Health Care initiative is sponsored by the California Health Care Foundation, The Commonwealth Fund, the Gordon and Betty Moore Foundation, The John A. Hartford Foundation, the Josiah Macy Jr. Foundation, the Robert Wood Johnson Foundation, and the National Academy of Medicine's Harvey V. Fineberg Impact Fund.

Role of the Funder/Sponsor: The funding agencies had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: This Special Communication reflects the views of the identified members of the National Academy of Medicine's Vital Directions for Health and Health Care initiative and does not represent formal consensus positions of the National Academies or the organizations of the participating authors.

Additional Contributions: Valuable assistance in preparation of the text was provided by Elizabeth Finkelman, MPP (National Academy of Medicine); she was compensated by the California Health Care Foundation, The Commonwealth Fund, the Gordon and Betty Moore Foundation, The John A. Hartford Foundation, the Josiah Macy Jr. Foundation, the Robert Wood Johnson Foundation, and the National Academy of Medicine's Harvey V. Fineberg Impact Fund.

Additional Information: Additional information on this and other National Academy of Medicine activities may be found at https://nam.edu/.

REFERENCES

1. Uberoi N, Finegold K, Gee E. Health insurance coverage and the Affordable Care Act, 2010-2016. March 3, 2016. https://aspe.hhs.gov/system/files/pdf/187551/ACA2010-2016.pdf. Accessed June 14, 2016.

2. Chetty R, Stepner M, Abraham S, et al. The association between income and life expectancy in the United States, 2001-2014. *JAMA*. 2016;315(16):1750-1766.

3. Xu JQ, Murphy SL, Kochanek KD, Arias E. *Mortality in the United States, 2015*. Hyattsville, MD: National Center for Health Statistics; 2016.

4. Topol E. How technology is transforming health care. 2013. http://health.usnews.com/health-news/hospital-of-tomorrow/articles/2013/07/12/how-technology-is-transforming-health-care. Accessed December 14, 2016.

5. Congressional Budget Office. Historical budget data, March 2016, and long-term budget projections, July 2016. https://www.cbo.gov/about/products/budget-economic-data. Accessed February 10, 2017.

6. Centers for Medicare & Medicaid Services. National health expenditure fact sheet. 2016. https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html. Accessed December 27, 2016.

7. Squires D, Anderson C. *U.S. Health Care From a Global Perspective: Spending, Use of Services, Prices, and Health in 13 Countries*. New York, NY: The Commonwealth Fund; 2015. http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2015/oct/1819_squires_us_hlt_care_global_perspective_oecd_intl_brief_v3.pdf. Accessed December 27, 2016.

8. Institute of Medicine. *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*. Washington, DC: National Academies Press; 2013.

9. Berwick DM, Hackbarth AD. Eliminating waste in US health care. *JAMA*. 2012;307(14):1513-1516.

10. McGinnis JM, Berwick DM, Daschle TA, et al. *Systems Strategies for Better Health Throughout the Life Course: A Vital Direction for Health and Health Care*. Washington, DC: National Academy of Medicine; 2016.

11. Institute of Medicine. *Evidence-Based Medicine and the Changing Nature of Health Care: 2007 IOM Annual Meeting Summary*. Washington, DC: National Academies Press; 2008.

12. McGinnis JM, Williams-Russo P, Knickman JR. The case for more active policy attention to health promotion. *Health Aff (Millwood)*. 2002;21(2):78-93.

13. Mitchell E. Population-based payment models: overcoming barriers, accelerating adoption. May 16, 2016. https://hcp-lan.org/2016/05/pbp-models-overcoming-barriers-accelerating-adoption/. Accessed December 27, 2016.

14. McGinnis JM, Foege WH. Actual causes of death in the United States. *JAMA*. 1993;270(18):2207-2212.

15. Taylor LA, Coyle CE, Ndumele C, et al. *Leveraging the Social Determinants of Health: What Works?* Boston, MA: Blue Cross Blue Shield of Massachusetts Foundation; 2015. http://bluecrossfoundation.org/sites/default/files/download/publication/Social_Equity_Report_Final.pdf. Accessed December 27, 2016.

16. Substance Abuse and Mental Health Services Administration. Health homes and medical homes. http://www.integration.samhsa.gov/integrated-care-models/health-homes. Accessed January 31, 2017.

17. McClellan MB, Leavitt MO. Competencies and tools to shift payments from volume to value. *JAMA*. 2016;316(16):1655-1656.

18. Légaré F, Witteman HO. Shared decision making: examining key elements and barriers to adoption into routine clinical practice. *Health Aff (Millwood)*. 2013;32(2):276-284.

19. Kish LJ, Topol EJ. Unpatients—why patients should own their medical data. *Nat Biotechnol*. 2015;33(9):921-924.

20. Vernon JA, Trujillo A, Rosenbaum S, DeBuono B. *Low Health Literacy: Implications for National Health Policy*. Washington, DC: Department of Health Policy, School of Public Health & Health Services, George Washington University; 2007.

21. Berman M, Fenaughty A. Technology and managed care: patient benefits of telemedicine in a rural health care network. *Health Econ*. 2005;14(6):559-573.

22. Hailey D, Roine R, Ohinmaa A. Systematic review of evidence for the benefits of telemedicine. *J Telemed Telecare*. 2002;8(suppl 1):1-30.

23. Krumholz HM, Bourne PE, Kuntz RE, Paz HL, Terry SF, Waldstreicher J. *Data Acquisition, Curation, and Use for a Continuously Learning Health System: A Vital Direction for Health and Health Care*. Washington, DC: National Academy of Medicine; 2016.

24. Patient-Centered Outcomes Research Institute. Communication and dissemination research. http://www.pcori.org/about-us/our-programs/communication-and-dissemination-research. Accessed January 27, 2017.

25. Stanford School of Medicine. Healthcare disparities and barriers to health care: rural health fact sheet. 2010. http://ruralhealth.stanford.edu/health-pros/factsheets/downloads/rural_fact_sheet_5.pdf. Accessed January 31, 2017.

26. National Academies of Sciences, Engineering, and Medicine. *Communities in Action: Pathways to Health Equity*. Washington, DC: National Academies Press; 2017.

27. Bradley EH, Taylor LA. *The American Health Care Paradox: Why Spending More Is Getting Us Less*. New York, NY: PublicAffairs; 2013.

28. Mitchell EM. Concentration of health expenditures in the US civilian noninstitutionalized population, 2014. November 2016. https://meps.ahrq.gov/data_files/publications/st497/stat497.shtml. Accessed February 2, 2017.

29. Center for Health Care Strategies and State Health Access Data Assistance Center. Community care teams: an overview of state approaches. March 2016. http://www.chcs.org/media/Community-Care-Teams-An-Overview-of-State-Approaches-030316.pdf. Accessed January 31, 2017.

30. Office of the National Coordinator for Health Information Technology. Information technology in health care: the next consumer revolution. 2013. https://www.healthit.gov/patients-families/benefits-health-it. Accessed December 27, 2016.

31. Perlin JB, Baker DB, Brailer DJ, et al. *Information Technology Interoperability and Use for Better Care and Evidence: A Vital Direction for Health and Health Care*. Washington, DC: National Academy of Medicine; 2016.

32. Office of the National Coordinator for Health Information Technology. Connecting health and care for the nation: a 10-year vision to achieve an interoperable health IT infrastructure. 2014. https://www.healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf. Accessed December 12, 2016.

33. Institute of Medicine. *Vital Signs: Core Metrics for Health and Health Care Progress*. Washington, DC: National Academies Press; 2015.

34. Pronovost PJ, Austin JM, Cassel CK, et al. *Fostering Transparency in Outcomes, Quality, Safety, and Costs: A Vital Direction for Health and Health Care*. Washington, DC: National Academy of Medicine; 2016.

35. Austin JM, McGlynn EA, Pronovost PJ. Fostering transparency in outcomes, quality, safety, and costs. *JAMA*. 2016;316(16):1661-1662.

36. Kruse J. Fragmentation in US medical education, research, and practice: the need for system wide defrag. *Fam Med*. 2013;45(1):54-57.

37. Lipstein SH, Kellermann AL, Berkowitz B, et al. *Workforce for 21st-Century Health and Health Care: A Vital Direction for Health and Health Care*. Washington, DC: National Academy of Medicine; 2016.

38. Zerhouni E, Berg JM, Hrabowski FA, Kington R, Landis SCR. *Training the Workforce for 21st Century Science: A Vital Direction for Health and Health Care*. Washington, DC: National Academy of Medicine; 2016.

39. Network for Excellence in Health Innovation. *Real World Evidence: A New Era for Health Care Innovation*. Cambridge, MA: Network for Excellence in Health Innovation; 2015.

40. Kennedy-Martin T, Curtis S, Faries D, Robinson S, Johnston J. A literature review on the representativeness of randomized controlled trial samples and implications for the external validity of trial results. *Trials*. 2015;16:495.

41. Krumholz HM, Terry SF, Waldstreicher J. Data acquisition, curation, and use for a continuously learning health system. *JAMA*. 2016;316(16):1669-1670.

42. Rosenblatt M, Boutin MM, Nussbaum SR. Innovation in medicine and device development, regulatory review, and use of clinical advances. *JAMA*. 2016;316(16):1671-1672.

43. Moses H III, Matheson DHM, Cairns-Smith S, George BP, Palisch C, Dorsey ER. The anatomy of medical research: US and international comparisons. *JAMA*. 2015;313(2):174-189.

44. Rosenblatt M, Austin CP, Boutin M, et al. *Innovation in Development, Regulatory Review, and Use of Clinical Advances: A Vital Direction for Health and Health Care*. Washington, DC: National Academy of Medicine; 2016.

45. US Food and Drug Administration. National Medical Evidence Generation Collaborative (EvGen Collaborative). https://www.fda.gov/ScienceResearch/SpecialTopics/EvGenSystem/default.htm. Accessed January 27, 2017.

By Victor J. Dzau, Mark B. McClellan, J. Michael McGinnis, Jessica C. Marx, Rebecca D. Sullenger, and William ElLaissi

DOI: 10.1377/hlthaff.2020.02204
HEALTH AFFAIRS 40, NO. 2 (2021): 197–203

COMMENTARY

Vital Directions For Health And Health Care: Priorities For 2021

ABSTRACT In 2016, in anticipation of the US presidential election and forthcoming new administration, the National Academy of Medicine launched a strategic initiative to marshal expert guidance on pressing health and health care priorities. Published as Vital Directions for Health and Health Care, the products of the initiative provide trusted, nonpartisan, evidence-based analysis of critical issues in health, health care, and biomedical science. The current collection of articles published in *Health Affairs* builds on the initial Vital Directions series by addressing a set of issues that have a particularly compelling need for attention from the next administration: health costs and financing, early childhood and maternal health, mental health and addiction, better health and health care for older adults, and infectious disease threats. The articles also reflect the current experience with both the coronavirus disease 2019 (COVID-19) pandemic and the health inequities that have been drawn out sharply by COVID-19, as well as the implications going forward for action.

Victor J. Dzau (vdzau@nas.edu) is the president of the National Academy of Medicine, in Washington, D.C.

Mark B. McClellan is the Robert J. Margolis Professor of Business, Medicine, and Policy and director of the Duke-Margolis Center for Health Policy at Duke University, in Durham, North Carolina, and Washington, D.C.

J. Michael McGinnis is the executive officer at the National Academy of Medicine.

Jessica C. Marx is a program officer at the National Academy of Medicine.

Rebecca D. Sullenger is a research assistant at the National Academy of Medicine.

William ElLaissi is the managing director of the Emory Healthcare Innovation Hub, in Atlanta, Georgia.

With its congressional charter as advisor to the nation and in anticipation of the 2016 US presidential election and forthcoming new administration, in 2016 the National Academy of Medicine launched a strategic initiative to marshal expert insights on health and health care priorities. Published as Vital Directions for Health and Health Care, the products of the initiative provided trusted, nonpartisan, evidence-based analysis of critical issues in health, health care, and biomedical science.

In its initial series, the project engaged more than 150 experts, who undertook analysis of compelling policy opportunities across nineteen key areas important to progress in three domains: better health and well-being, high-value health care, and strong science and technology.[1] The resulting framework from this initiative is organized into eight crosscutting policy directions for all levels of leadership, including four action priorities (pay for value, empower people, activate communities, and connect care) and four essential infrastructure needs (measure what matters most, modernize skills, accelerate real-world evidence, and advance science). Together, these policy directions serve as a foundation for the US to achieve its vision for a health system that performs optimally in improving the health of the population; promoting, protecting, and restoring the health of individuals; and helping each person reach their full potential for health and well-being.[2]

Since the 2016 publication of Vital Directions, much has happened in health and health care, underscoring concerns about the nation's persistent challenges related to maternal mortality, child health and development, behavioral health, the opioid crisis, and pervasive health inequities, among others. These developments, coupled with the emergence of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) and the coronavirus disease 2019 (COVID-

19) pandemic, in the context of another US presidential election, prompt the need for renewed assessment of health care priorities and guidance. In addressing these challenges, the next administration must combat the health disparities that have negatively affected Black people, Indigenous people, and other people of color for decades and prioritize the pursuit of health equity for all Americans.[3] The COVID-19 pandemic has further exacerbated racial health inequities across public health and health care systems in the US.

This collection of articles published in *Health Affairs* builds on the initial Vital Directions series by selecting a set of issues with a particularly compelling need for leadership and decision making at multiple levels. Accordingly, the articles highlight five topical areas: health costs and financing, early childhood and maternal health, mental health and addiction, better health and health care for older adults, and infectious disease threats. All of these articles highlight the crosscutting theme of the disproportionate negative impact of health inequities on vulnerable and underserved populations and the importance of giving the highest priority to eliminating these inequities. The articles also reflect the current experience with the COVID-19 pandemic at the time of writing and the implications for action going forward.

An Unprecedented Juncture

During the past four years the US health system has confronted unprecedented challenges and uncertainties. The period began with heated debate about the repeal of the Affordable Care Act of 2010, and the law's implementation and revision remain active topics of discussion and debate. Then 2019–20 saw the emergence of COVID-19 and the dramatic escalation of public attention to long-standing racial and ethnic disparities in society as a whole, with health care being an arena where those disparities are particularly pronounced.

A persistent and serious challenge has been health care expenditures,[4] with US health expenditures as a proportion of gross domestic product continuing to far outstrip comparable expenditures in other Organization for Economic Cooperation and Development countries. To compound the problem, Americans continue to have worse health outcomes even in the face of such high expenditures, including lower life expectancy, higher suicide rates, and a higher chronic disease burden, with people of color suffering disproportionately.[5] Partly as a result of high costs, access to care is often limited and unequal. Of the estimated 20.3 million Americans with substance use disorder, 89.8 percent did not receive treatment in 2018.[6] Disparities between racial groups in maternal mortality persist, with mortality rates for non-Hispanic Black women remaining more than double those of their non-Hispanic White counterparts.[7]

The tragedy of these disproportionate burdens has been underscored in the experience of the COVID-19 pandemic. As of January 5, 2021, the Centers for Disease Control and Prevention (CDC) reported 20,732,404 cumulative COVID-19 cases and 352,464 total deaths due to SARS-CoV-2 in the US.[8] In addition to pandemic-related morbidity and mortality, US unemployment rates reached a peak of 14.7 percent in April 2020 and continued to persist at a higher-than-average rate of 6.7 percent as of November 2020.[9] Furthermore, the associated school closures have disrupted the education of millions of American children.[10] COVID-19 also has exacerbated health disparities in the US. Black, Indigenous, Pacific Islander, and Latino Americans are proportionately more likely than White Americans to die from COVID-19,[11] accentuating the urgency of the need for action to address health inequities. An effective approach will require multisector collaboration that considers the social determinants of health, confronts economic inequities, and rejects policies that perpetuate structural racism.

High-Priority Challenges

Each of the five topical articles published in Vital Directions: Priorities for 2021 reviews the status and trends for the problem, the priorities involved, an analysis of approaches, and reflections on strategies to address the problem. Of particular importance, as reflected throughout all of the articles, is the clear and urgent obligation for the US to turn its full attention to the growing problem of health inequities and to the structural racism that perpetuates such disparities.

HEALTH COSTS AND FINANCING: CHALLENGES AND STRATEGIES Despite high health care expenditures,[12] Americans generally experience poorer health outcomes compared with their counterparts in other high-income countries.[5] Not surprisingly, many Americans are concerned about US health care costs, making health reform one of the most prominent current political issues.[13] The COVID-19 pandemic has highlighted the weaknesses of the US health system and exacerbated already prevalent health disparities across the nation.[14,15] Rising numbers of uninsured people[16] that have worsened during the pandemic,[17] high costs of novel therapeutics,[12] and access barriers underscore the need

There is an urgent need to provide more equitable access to affordable health care in the interest of national public health.

for health reform. The article "Health Costs and Financing: Challenges and Strategies for a New Administration," by William Shrank and colleagues, takes a deeper look into these issues and provides recommendations to improve the efficacy and efficiency of the US health care system in the context of the COVID-19 pandemic and beyond, with explicit consideration of how to address disparities in outcomes to improve equity in doing so.[18]

Given the high costs and substandard health outcomes of the US health system, ensuring effective and high-value health care for all Americans must be a top priority for the next administration. There is an urgent need to provide more equitable access to affordable health care in the interest of national public health. To achieve these goals, the US will need to develop innovative ways of improving access to coverage, address health provider workforce shortages in areas such as primary care,[17] and reform health care payment methods. Recent shifts to value-based payment have sometimes resulted in significant savings, especially models that move farther away from fee-for-service payment.[19] A continued shift to alternative payment methods, including population-based payment with an emphasis on accountability for addressing health disparities, may decrease future costs while improving care.[20]

As part of these reforms, there are clear opportunities for telehealth services, therapeutic innovations, and health care data sharing. Although telehealth visits have significantly increased since the beginning of the COVID-19 pandemic[21] and multiple payers have expanded reimbursement for these services,[22] future telehealth regulations and reimbursement remain uncertain. The federal government will also need to reexamine the regulatory and reimbursement frameworks for medical therapeutics and health care data with a focus on supporting value and encouraging innovative models of care. The cost of therapeutics is not always aligned with the benefits they provide, and high prices limit access to pharmaceuticals for many Americans.[23] Patients also experience difficultly in gaining access to their own health information because of a lack of robust data systems accessible to both public and private providers.[24] To address these challenges, Shrank and colleagues present near-term opportunities to improve access, affordability, and equity, as well a list of recommendations for key elected officials and political appointees.

OPTIMIZING HEALTH AND WELL-BEING FOR WOMEN AND CHILDREN Women and children continue to experience high rates of morbidity and mortality in the US, which are further intensified by racial inequities.[25] More than 700 women die each year in the US during pregnancy and childbirth, and non-Hispanic Black women are more than twice as likely to die during pregnancy and childbirth as White women.[26] The US also has high rates of prematurity—at a rate of one in ten newborns—which is a leading cause of infant mortality and lifelong morbidity. Compared with their peers in other countries, US children experience higher rates of poor health outcomes, such as developmental problems, mental health conditions, and severe asthma, coupled with and worsened by social and environmental stressors such as poverty and hunger. Notably, the prevalence of adverse childhood outcomes is higher for Black, Hispanic, and low-income children regardless of race or ethnicity.[27]

To address these issues, the article by Elena Fuentes-Afflick and colleagues, titled "Optimizing Health and Well-Being for Women and Children," adopts a life-course perspective to assess both causes for and solutions to issues in child and maternal health.[28] This framework underscores the impacts of both positive and negative cumulative health outcomes through multiple phases of life from preconception to adulthood and highlights the interrelatedness of each developmental phase. As the authors of this article express, "Maternal health and well-being . . . may determine the health of the next generation and, ultimately, the health of the nation." The cumulative impacts of poor health outcomes in early childhood reverberate throughout the life course.

The authors note that prevention is key to improving maternity care and health outcomes for childbearing women. Several state-level and national strategies, such as the California Maternal Quality Care Collaborative and the Maternal and Child Health Bureau's Alliance for Innovation in Maternal Health, use a quality improvement approach to improve health outcomes. Addressing coverage gaps in health care can also reduce ma-

ternal mortality; in 2018 there were 10.8 million uninsured adult women, and more than one million women in poverty fell into the ACA's "coverage gap" between Medicaid and subsidized Marketplace eligibility.[29] The authors note that the US should set the world's standard for promoting the health and well-being of women and children, and they provide recommendations for a health system that leads to successful outcomes by focusing on targeted and moonshot recommendations. The targeted recommendations focus on existing policies or programs that are eminently achievable, which include the following elements: data, safety, and research. The moonshot recommendations, which are transformative and require endorsement, support, and resources from multiple sectors, include the following elements: ensuring access, transforming health care delivery and financing, and addressing social and environmental factors.

TRANSFORMING MENTAL HEALTH AND ADDICTION SERVICES Behavioral health, mental health, and addiction significantly affect society in the US and around the world. As of 2018, 20.3 million Americans (ages twelve and older) had a substance use disorder, and 47.6 million American adults suffered from at least one mental illness.[6] Although the US has made some strides in improving access to treatment for behavioral health conditions, significant gaps in care remain. Barriers to quality care are particularly high for people of color and people with socioeconomic disadvantage, emphasizing the need for special consideration of vulnerable populations in policies relevant to behavioral health.[30] Improving mental health and addiction treatment for all Americans requires combating stigma and promoting evidence-based, comprehensive care. In their article, "Transforming Mental Health and Addiction Services," Margarita Alegría and colleagues discuss the most pressing needs in behavioral health care and offer policy solutions that call for a reconceptualization of the behavioral health care system to prioritize the social needs of patients and to foster greater support of the behavioral health workforce.[31]

Current behavioral health interventions often focus on volume of services and symptom reduction as a benchmark for success. However, given scientific advancements and improvements in patient-centered care, people with mental illness are increasingly in recovery and able to live full lives despite their symptoms. Thus, it is possible to move beyond symptom reduction and to emphasize everyday functioning and societal involvement in behavioral health care.[32] A shift toward prioritizing social context and addressing the social needs of patients with behavioral health conditions will be a vital part of behavioral health care going forward. Further, improving functional outcomes requires transforming the behavioral health system to meet patients "where they are" in terms of physical location and their current acceptance of their illness. Promotion of community-based organization outreach,[33] telehealth services,[34] and home visiting programs[35] to augment behavioral health care presents an opportunity to expand patient enrollment in care and diagnose disease sooner.

US leaders must address the preventable health disparities that negatively affect millions of Americans.

Another pressing need in the advancement of mental health and addiction care is decriminalization of people who have behavioral health conditions, based on the recognition that addiction is a brain disease.[36] Such change is urgently needed both to improve health outcomes and because people of color are disproportionately negatively affected by the criminal justice system.[37] Efforts to improve behavioral health outcomes should include a reconfiguration of the crisis response system with a workforce trained in deescalation tactics instead of criminalization.[38]

ACTUALIZING BETTER HEALTH AND HEALTH CARE FOR OLDER ADULTS By 2040, people ages sixty-five and older are predicted to account for 21.6 percent of the US population, and resources will need to be appropriately allocated to ensure that they receive person-centered, high-quality care.[39] The COVID-19 pandemic has further exposed the consequences of fragmented and unequal care for older adults, as well as the enduring impacts of structural racism. To address systemic inequities and to address many of the challenges facing older adults, it is imperative to take a population health approach. By actualizing this vision of population health for older adults, the nation can address many of the outstanding challenges and issues faced by older Americans.

In their article, "Actualizing Better Health and Health Care for Older Adults," Terry Fulmer and colleagues address core challenges facing

health and health care for older adults, ranging from recruitment in the geriatrics workforce a nd digital health barriers to the importance of age-friendly public health systems and addressing social isolation.[40] As the population of older adults continues to rise during the next decade, it will be important that the geriatrics workforce—ranging from specialists to caregivers—expands to meet the increase in demand for care. As of 2018 the older adult population in the US was 49.2 million; however, there were only 3,590 full-time practicing geriatricians.[41] Equally important are the issues faced by the geriatrics workforce—especially issues worsened or brought on by the COVID-19 pandemic, which range from burnout[42] to specific hardships faced by nursing home staff and paid caregivers. A disproportionate number of all deaths from COVID-19 in the US are tied to nursing facilities, and working in these facilities increases the risk for transmission to exposure among patients and staff.

Telehealth is an important innovation, especially within the context of the pandemic, to increase access to care. However, barriers remain for engagement via virtual platforms, including limited digital health literacy, unequal access to technology, design barriers, and integration of telehealth with other services needed for effective care. An additional concern for care delivery for older adults is that public health funding is often disease or condition specific rather than population focused, yet the development of age-friendly health systems is integral to promoting healthy aging. Redesigning long-term services and supports is also a critical challenge that must be addressed, especially given that twelve million adults are living with serious illness. Innovative long-term care should provide more support for older adults remaining at home and aging in place. The disproportionate mortality rates resulting from COVID-19, particularly in nursing homes, also highlight the importance of improving care quality in long-term care facilities and other community living arrangements.

To address these challenges, the authors identify six vital directions to improve the care and quality of life for older Americans: create an adequately prepared workforce for the health care of older people; strengthen the role of public health; promote equity and address the social determinants of health; develop, evaluate, and implement new approaches to the delivery of health care for older adults that incorporate evidence-based telehealth and technology; allocate resources to support person-centered care including palliative and end-of-life care; and redesign the structure and financing of long-term services and supports, including nursing home and community care.

INFECTIOUS DISEASE THREATS: A REBOUND TO RESILIENCE During the past five years there have been increasingly serious infectious disease threats in the US and globally, ranging from new foodborne and drug-resistant pathogens to antimicrobial resistance and vectorborne diseases such as Zika. However, COVID-19 in particular has tested the US response and resilience to global threats, revealing the importance of national and international coordinated responses to pandemics. The economic, political, and social impacts of COVID-19 will continue to demand ongoing attention in 2021, remaining significant challenges. Further responses should aim to improve resilience against future infectious disease threats.

In "Infectious Disease Threats: A Rebound to Resilience," Peter Daszak and colleagues outline key lessons learned from more than a century of pandemics and those yet to be learned from the COVID-19 experience.[43] Infectious disease epidemics and pandemics result in dire health, social, and economic consequences, with significant impacts on underserved and disenfranchised communities. In particular, the COVID-19 pandemic has disproportionally affected hospitalization and mortality rates for communities of color, people with disabilities, people in detention, and elderly populations.

Daszak and colleagues propose six critical steps to build resilience to address the current pandemic and also to prepare for future infectious disease threats. These recommendations call for launching an expert Pandemic Preparedness and Response Commission, reinforcing a science-based approach to public health policy, and increasing federal funding to agencies involved in pandemic preparedness and control. Across all of these recommendations, and especially for an effective response to COVID-19, structural changes to the US public health system and infrastructure are essential to addressing infectious disease threats, as is collaboration among federal agencies and state governments. The authors maintain that evidence-based national leadership, in coordination with public health guidance, is critical to preventing and containing pandemics. The role of the US as global leader in pandemic response and recovery not only protects Americans in the short and long term but also promotes global health security in the face of potential future threats.

Health Equity: The Most Vital Direction For 2021

The unacceptable health inequities that persist in the US today, compounded by the enormous

and uneven impact of the COVID-19 pandemic, emphasize the need and the opportunity for the next administration to address the fundamental challenges that the nation faces in health and health care. US leaders must address the preventable health disparities that negatively affect millions of Americans and regain the public's trust in health science. Across the articles contained in the 2021 Vital Directions series is the clear message to the nation—and those stewarding health policy—that the most fundamental obligation is to view health system reform through a health equity lens. It is incumbent on all involved to advance an evidence-based and population-engaged assessment of the equity implications of every policy, program, and activity in the health sector, including those related to payment reform; reach and operation of the digital health infrastructure; links among health care, public health, and social services; the adequacy and nature of the workforce; and the focus and conduct of health and biomedical research. With myriad interacting public and private players and policies shaping health and health outcomes, the health sector cannot in isolation correct health, social, and racial inequities. But those of us in the health field—clinicians, patients, health organizations, public health and social service agencies, payers, manufacturers, and policy makers—constitute a powerful force for leadership. Testament to the importance of that leadership is the core message of Vital Directions 2021, and it is a message that will be prominent as the National Academy of Medicine works with partners throughout the nation to ensure that every American reaches their full potential for health and well-being. ■

The views presented in this publication are those of individual contributors and do not represent formal consensus positions of the authors' organizations; the National Academy of Medicine (NAM); or the National Academies of Sciences, Engineering, and Medicine. The NAM thanks the sponsors of Vital Directions 2021, whose support made this work possible. This collection of articles is funded in part by the Robert Wood Johnson Foundation, The John A. Hartford Foundation, and the Gordon and Betty Moore Foundation. Additional information on this and other NAM activities may be found at NAM.edu.

NOTES

1 Dzau VJ, McClellan M, McGinnis JM. Vital Directions for Health and Health Care: an initiative of the National Academy of Medicine. JAMA. 2016;316(7):711–2.

2 Dzau VJ, McClellan M, Burke SP, Coye MJ, Daschle TA, Diaz A, et al. Vital Directions for Health and Health Care: priorities from a National Academy of Medicine initiative. In: Dzau VJ, McClellan M, McGinnis JM, Finkelman EM, editors. Vital Directions for Health and Health Care: an initiative of the National Academy of Medicine [Internet]. Washington (DC): National Academy of Medicine; 2017 [cited 2020 Dec 22]. p. 1–38. Available from: https://nam.edu/wp-content/uploads/2018/02/Vital-Directions-for-Health-and-Health-Care-Final-Publication-022718.pdf

3 Weinstein JN, Geller A, Negussie Y, Baciu A, editors. Communities in action: pathways to health equity. Washington (DC): National Academies Press; 2017.

4 Kamal R, McDermott D, Cox C. How has U.S. spending on healthcare changed over time? [Internet]. San Francisco (CA): Peterson-KFF Health System Tracker; 2019 Dec 20 [cited 2020 Dec 4]. Available from: https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time/#item-start

5 Tikkanen R, Abrams MK. U.S. health care from a global perspective, 2019: higher spending, worse outcomes? [Internet]. New York (NY): Commonwealth Fund; 2020 Jan 30 [cited 2020 Dec 4]. Available from: https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/us-health-care-global-perspective-2019

6 McCance-Katz EF. The National Survey on Drug Use and Health: 2018 [Internet]. Rockville (MD): Substance Abuse and Mental Health Services Administration; 2019 [cited 2020 Dec 4]. Available from: https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/Assistant-Secretary-nsduh2018_presentation.pdf

7 National Center for Health Statistics. Maternal mortality [Internet]. Hyattsville (MD): NCHS; [cited 2020 Dec 4]. Available from: https://www.cdc.gov/nchs/maternal-mortality/index.htm

8 Centers for Disease Control and Prevention. United States COVID-19 cases and deaths by state [Internet]. Atlanta (GA): CDC; 2021 Jan 5 [cited 2021 Jan 14]. Available from: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html

9 Congressional Research Service. Unemployment rates during the COVID-19 pandemic: in brief [Internet]. Washington (DC): CRS; [last updated 2020 Nov 6; cited 2020 Dec 16]. Available from: https://fas.org/sgp/crs/misc/R46554.pdf

10 Christakis DA, Van Cleve W, Zimmerman FJ. Estimation of US children's educational attainment and years of life lost associated with primary school closures during the coronavirus disease 2019 pandemic. JAMA Netw Open. 2020;3(11):e2028786.

11 APM Research Lab Staff. The color of coronavirus: COVID-19 deaths by race and ethnicity in the U.S. [Internet]. Saint Paul (MN): APM Research Lab; 2020 Nov 12 [cited 2020 Dec 4]. Available from: https://www.apmresearchlab.org/covid/deaths-by-race

12 Papanicolas I, Woskie LR, Jha AK. Health care spending in the United States and other high-income countries. JAMA. 2018;319(10):1024–39.

13 Kirzinger A, Kearney A, Brodie M. KFF Health Tracking Poll—February 2020: health care in the 2020 election [Internet]. Washington (DC): Henry J. Kaiser Family Foundation; 2020 Feb 21 [cited 2020 Dec 4]. Available from: https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2020/

14 Buchmueller TC, Levy HG. The ACA's

impact on racial and ethnic disparities in health insurance coverage and access to care. Health Aff (Millwood). 2020;39(3):395–402.
15 Dorn AV, Cooney RE, Sabin ML. COVID-19 exacerbating inequalities in the US. Lancet. 2020;395(10232):1243–4.
16 Keehan SP, Cuckler GA, Poisal JA, Sisko AM, Smith SD, Madison AJ, et al. National health expenditure projections, 2019–28: expected rebound in prices drives rising spending growth. Health Aff (Millwood). 2020;39(4):704–14.
17 Health Resources and Services Administration. Health workforce projections [Internet]. Rockville (MD): HRSA; 2020 Sep [cited 2020 Dec 4]. Available from: https://bhw.hrsa.gov/health-workforce-analysis/research/projections
18 Shrank WH, DeParle N, Gottlieb S, Jain SH, Orszag P, Powers BW, et al. Health costs and financing: challenges and strategies. Health Aff (Millwood). 2021;40(2):235–42.
19 McWilliams JM, Hatfield LA, Landon BE, Hamed P, Chernew ME. Medicare spending after 3 years of the Medicare shared savings program. N Engl J Med. 2018;379(12):1139–49.
20 Health Care Payment Learning & Action Network. APM measurement progress of alternative payment models: 2019 methodology and results report [Internet]. Bedford (MA): HCPLAN; 2019 [cited 2020 Dec 4]. Available from: http://hcplan.org/workproducts/apm-methodology-2019.pdf
21 Mehrotra A, Chernew M, Linetsky D, Hatch H, Cutler D (Harvard University; Cambridge, MA). The impact of the COVID-19 pandemic on outpatient visits: practices are adapting to the new normal [Internet]. New York (NY): Commonwealth Fund; 2020 Jun 25 [cited 2020 Dec 4]. Available from: https://www.commonwealthfund.org/publications/2020/jun/impact-covid-19-pandemic-outpatient-visits-practices-adapting-new-normal
22 Department of Health and Human Services. Telehealth: delivering care safely during COVID-19 [Internet]. Washington (DC): HHS [cited 2020 Dec 4]. Available from: https://www.hhs.gov/coronavirus/telehealth/index.html
23 Henry J. Kaiser Family Foundation [Internet]. San Francisco (CA): KFF; 2019. Press release, Poll: nearly 1 in 4 Americans taking prescription drugs say it's difficult to afford their medicines, including larger shares among those with health issues, with low incomes and nearing Medicare age; 2019 Mar 1 [cited 2020 Dec 4]. Available from: https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/
24 Olson Grande T, Adams D, Marchibroda J, Hoagland GW, Adler-Milstein J, Segal M. Advancing interoperability, information sharing, and data access: improving health and healthcare for Americans [Internet]. Washington (DC): Bipartisan Policy Center; 2019 Feb 12 [cited 2020 Dec 4]. Available from: https://bipartisanpolicy.org/report/advancing-interoperability-information-sharing-and-data-access-improving-health-and-health care-for-americans/
25 DeVoe JE, Geller A, Negussie Y, editors. Vibrant and healthy kids: aligning science, practice, and policy to advance health equity. Washington (DC): National Academies Press; 2019.
26 Centers for Disease Control and Prevention. Pregnancy-related deaths [Internet]. Atlanta (GA): CDC; [last reviewed 2019 Feb 26; cited 2021 Jan 14]. Available from: https://www.cdc.gov/reproductive health/maternalinfanthealth/pregnancy-relatedmortality.htm
27 Slopen N, Shonkoff JP, Albert MA, Yoshikawa H, Jacobs A, Stoltz R, et al. Racial disparities in child adversity in the U.S.: interactions with family immigration history and income. Am J Prev Med. 2016;50(1):47–56.
28 Fuentes-Afflick E, Perrin J, Moley KH, Diaz Á, McCormick M, Lu MC. Optimizing health and well-being for women and children. Health Aff (Millwood). 2021;40(2):212–8.
29 Henry J. Kaiser Family Foundation. Women's health insurance coverage [Internet]. San Francisco (CA): KFF; 2020 Jan 24 [cited 2020 Dec 4]. Available from: https://www.kff.org/womens-health-policy/fact-sheet/womens-health-insurance-coverage-fact-sheet/
30 Agency for Healthcare Research and Quality. National healthcare quality and disparities report 2018 [Internet]. Rockville (MD): AHRQ; 2019 Sep [cited 2020 Dec 4]. Available from: https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/2018qdr.pdf
31 Alegría M, Frank RG, Hansen HB, Sharfstein JM, Shim RS, Tierney M. Transforming mental health and addiction services. Health Aff (Millwood). 2021;40(2):226–34.
32 Davidson L. The recovery movement: implications for mental health care and enabling people to participate fully in life. Health Aff (Millwood). 2016;35(6):1091–7.
33 Alegría M, Frontera W, Cruz-Gonzalez M, Markle SL, Trinh-Shevrin C, Wang Y, et al. Effectiveness of a disability preventive intervention for minority and immigrant elders: the Positive Minds—Strong Bodies randomized clinical trial. Am J Geriatr Psychiatry. 2019;27(12):1299–313.
34 Mehrotra A, Huskamp HA, Souza J, Uscher-Pines L, Rose S, Landon BE, et al. Rapid growth in mental health telemedicine use among rural Medicare beneficiaries, wide variation across states. Health Aff (Millwood). 2017;36(5):909–17.
35 Goodson BD, Mackrain M, Perry DF, O'Brien K, Gwaltney MK. Enhancing home visiting with mental health consultation. Pediatrics. 2013;132(Suppl 2):S180–90.
36 National Institute on Drug Abuse. DrugFacts: Understanding drug use and addiction [Internet]. Bethesda (MD): NIDA; 2018 Jun 6 [cited: 2020 Dec 4]. Available from: https://www.drugabuse.gov/publications/drugfacts/understanding-drug-use-addiction
37 Thompson M. Race, gender, and the social construction of mental illness in the criminal justice system. Sociol Perspect. 2010;53(1):99–125.
38 Dempsey C, Quanbeck C, Bush C, Kruger K. Decriminalizing mental illness: specialized policing responses. CNS Spectr. 2020;25(2):181–95.
39 Administration for Community Living, Administration on Aging. 2018 profile of older Americans [Internet]. Washington (DC): Department of Health and Human Services; 2018 Apr [cited 2020 Dec 16]. Available from: https://acl.gov/sites/default/files/Aging%20and%20Disability%20in%20America/2018OlderAmericansProfile.pdf
40 Fulmer T, Reuben DB, Auerbach J, Fick DM, Galambos C, Johnson KS. Actualizing better health and health care for older adults. Health Aff (Millwood). 2021;40(2):219–25.
41 American Geriatrics Society. Geriatrics workforce by the numbers: state of the geriatrician workforce [Internet]. New York (NY): AGS; [cited 2020 Dec 4]. Available from: https://www.americangeriatrics.org/geriatrics-profession/about-geriatrics/geriatrics-workforce-numbers
42 Dzau VJ, Kirch D, Nasca T. Preventing a parallel pandemic—a national strategy to protect clinicians' well-being. N Engl J Med. 2020;383(6):513–5.
43 Daszak P, Keusch GT, Phelan AL, Johnson CK, Osterholm MT. Infectious disease threats: a rebound to resilience. Health Aff (Millwood). 2021;40(2):204–11.

UCSF School of Pharmacy

Global Medi-Cal DUR Updates: Q1 2022

Shal Lynch, PharmD, CGP
- Health Sciences Associate Clinical Professor, Dept of Clinical Pharmacy

Amanda R. Fingado, MPH
- Senior Epidemiologist/Statistician, Dept of Clinical Pharmacy

Ally Diiorio, PharmD
- PGY1 Managed Care Pharmacy Resident, Dept of Clinical Pharmacy

Topics for Discussion

- Publications
  - February 2022: Buprenorphine
- Educational Outreach
  - Final Outcomes: Dental Pain Letter
  - Retrospective Naloxone Study
  - Prospective Naloxone Study

Topics for Discussion (cont.)

- Retrospective DUR
  - FFS Annual Report to CMS: FFY 2021
  - Global Quarterly Report: 4Q2021 (October – December 2021)
  - Global Annual Report: Calendar Year 2021
  - Quarterly DUR Report: 1Q2022 (January – March 2022)
  - Evaluation Report: 1Q2022 (January – March 2022)
  - Core Set Measures: Care of Acute and Chronic Conditions
- Fee-for-Service Prospective DUR: New GCNs Q1 2022

DUR Publications

- February 2022: Alert
  - Professional Organizations Push for Recall of Buprenorphine Dental Warning

Future Topics

Bulletins:

- Latent Tuberculosis Infection (publishing in May 2022)
- Updated ACOG guidelines for postpartum pain (in progress, July 2022)
- Annual immunization update (in progress, September 2022)
- Pharmacist furnishing of hormonal contraception
- Managing pain in population with comorbid mental health conditions
- Hypertension medication adherence

Alerts:

- California Immunization Registry (publishing in May 2022)
- Updated NAMS guidelines for hormone replacement therapy

Board questions/recommendations?

Background: Dental Pain Letter

- Both the ADA and the AAPD recommend non-opioid analgesics, such as non-steroidal anti-inflammatory drugs (NSAIDs) and acetaminophen for management of acute dental pain
- If use of opioids is warranted, the CDC recommends that clinicians prescribe the lowest effective dose and only for the expected duration of pain severe enough to require opioids
  - Three days or less will often be sufficient
  - More than seven days is rarely ever needed

Methods: Dental Pain Letter

- Objective was to inform dentists about the updated American Dental Association (ADA) and the American Academy of Pediatric Dentistry (AAPD) recommendations for the management of acute dental pain
- Letters were mailed in February of 2021 to the top 153 dentists by total paid claims for opioid medication exceeding 3 days' supply between March 1, 2019 – February 29, 2020
- Letters included the Medi-Cal DUR bulletin on dental prescribing and a provider survey

Primary Outcome: Dental Pain Letter

- Within 12 months following the mailing:
  - 44% decrease in paid claims for opioids among these prescribers (3,474 paid claims for opioids prescribed after mailing vs. 6,162 before mailing)
    - 50% decrease in paid claims for oxycodone (went from 22 prescribers to 3)
  - Average days' supply decreased from 4.9 to 4.4 days
  - Average number of tablets decreased from 20.3 to 18.8 tablets
  - 11 prescribers had no paid claims for opioids during this time

Secondary Outcome: Dental Pain Letter

- Within 12 months following the mailing:
  - 32% of paid claims for opioids had days' supply ≤ 3 (vs. 15% of paid claims prior to the mailing)
  - Among those paid claims with days' supply ≤ 3 the average number of tablets also decreased from 15.2 to 13.0 tablets
- 19% increase after the mailing in paid claims for non-opioid pain medications, including ibuprofen and acetaminophen
- Overall proportion of opioid claims went from 10.0% to 5.2%
- Provider response rate (18%) and returned mail rate (6%)

Board questions/recommendations?

UCSF

Retrospective Naloxone Study

- Based on research completed for the DUR Educational Article on Naloxone, which was published in December 2021
- Received IRB Approval from both UCSF and DHCS
- May 5, 2022
  - Poster presentation at the 24th Annual UCSF Department of Clinical Pharmacy Spring Research Symposium
- May 24, 2022
  - Poster presentation at the 2022 American College of Clinical Pharmacy Virtual Poster Symposium

UCSF

UCSF

Board questions/recommendations?

Prospective Naloxone Study: Background

- Increasing access to naloxone is critical to reduce mortality due to opioid overdose
  - In 2020, less than 50% percent of community pharmacies in California stocked naloxone[1]
  - Pharmacies in rural communities are even less likely to furnish and stock naloxone than urban areas[2]
  - In California, two of the highest rates of death due to opioid overdose during 2020 were reported among the rural communities of Lake County and Nevada County[3]

1. Puzantian T et al 2021. JAPhA.
2. Cid A et al 2021. Pharmacy (Basel)
3. California Opioid Overdose Surveillance Dashboard

Prospective Naloxone Study: Methods

- Sequential, mixed-methods approach with quantitative and qualitative assessments:
  1. Interviews with key stakeholders to identify barriers and understand past initiatives completed
  2. On-site visits to community pharmacies in Lake and Nevada County to survey pharmacy staff:
     - Survey questions will assess 1) attitudes held by pharmacy staff towards naloxone use, 2) perceived barriers to furnishing naloxone at the pharmacy, and 3) need for additional naloxone training

Prospective Naloxone Study: Aims

- Identify unique barriers and facilitators to furnish naloxone from community pharmacies in Lake County and Nevada County
- Understand prior naloxone distribution initiatives by local community organizations
- Assess attitudes and beliefs held by pharmacy staff regarding naloxone use

Prospective Naloxone Study: Timeline

- April 2022 – Received IRB approval
- Summer 2022 – Community pharmacy recruitment and complete stakeholder interviews
- Fall 2022 – Data analysis and preparation of final report
- Will provide updates to the Board at future meetings

Board questions/recommendations?

New GCN Alert Profiles

Background

- Each week new Generic Code Numbers (GCNs) are added
- Overutilization (ER), Drug-Pregnancy (PG) and Drug-Drug Interactions (DD) alerts are automatically turned on for all new GCNs
- New GCNs are reviewed weekly for additional alerts
- New GCNs with alerts turned on other than ER, PG, and DD are provided at each Board meeting for review

Updated Alerts: Q1 2022 Target Drugs

Drug Description	Alerts Turned On
CABOTEGRAVIR	ID
CELECOXIB/TRAMADOL	MC, TD, AT, ID, HD, LD
RILPIVIRINE	ID

KEY:

DA	Drug-Allergy
MC	Drug-Disease
TD	Therapeutic Duplication
LR	Late Refill
AT	Additive Toxicity
ID	Ingredient Duplication
PA	Drug-Age
HD	High Dose
LD	Low Dose

Board questions/recommendations? 6

Annual Report to CMS: FFY 2021

- Clarification on PDMP data tables
  - If unable to complete using PDMP data, leave blank and explain where indicated
  - Mandatory reporting of these data will be required in FFY2023
- April 11, 2022 – Release of the Optimized CURES
- Additional classes added under psychotropic medications section
  - Added ANTIDEPRESSANTS, MOOD STABILIZERS, and ANTIANXIETY/SEDATIVES
  - ANTIPSYCHOTICS and STIMULANTS were already included previously
- MCO reports are due to DHCS by June 1, 2022
- FFS and MCO reports must be submitted to CMS by June 30, 2022

Board questions/recommendations?

Global Quarterly Report: 4Q2021

- Vast majority of utilizing beneficiaries are MCP enrollees (range from 99% of OTLIC to 89% of OTHER)
- Total utilizing beneficiaries in the 0-12 years of age group increased by 44% between 4Q2020 and 4Q2021, most likely due to the COVID-19 vaccine for children between 5 and 12 years of age in 4Q2021
- Significant changes vs. prior year in total paid claims for:
  - AMOXICILLIN: 40%↑
  - ACETAMINOPHEN: 18%↑
  - HYDROCODONE/ACETAMINOPHEN: 5%↓

Board questions/recommendations?

Global Annual Report: Calendar Year 2021

- 51% of eligible Medi-Cal beneficiaries had a paid pharmacy claim through the Medi-Cal program in 2021
  - 21% of eligible FFS enrollees
  - 56% of eligible MCP enrollees
- FFS enrollees were 23% of eligible beneficiaries, 9% of utilizing beneficiaries, and 6% of total paid claims
- 12% increase in utilizing beneficiaries and 4% increase in total paid claims from 2020, driven by COVID-19 vaccines

Board questions/recommendations?

Quarterly Report: 1Q2022

- 53,153,578 Medi-Cal Rx claims submitted for processing in Q1
  - 53% Paid – claim processed and paid
  - 16% Denied – claim processed but found to be unpayable
  - 20% Reversed – claim reversed after it was processed and paid
  - 10% Rejected – claim contained errors that prevented processing
  - < 1% Duplicate – claim was found to be a duplicate of another claim
- 28% of claims generated DUR messages or alerts
- 31% of eligible Medi-Cal Rx beneficiaries had a paid claim in Q1

Board questions/recommendations?

Quarterly Evaluation Report: 1Q2022

- One articles to evaluate from 1Q2020:
  - Drug Safety Communication: Mental Health Side Effects from Montelukast – January 2020

Montelukast Evaluation: Purpose

- Review the FDA safety communications on montelukast since the publication of the original article and describe any relevant updates

Montelukast Evaluation: Updates

- No additional alerts related to FDA safety concerns
- Outreach letter to providers regarding montelukast was sent by the DUR program on April 24, 2020
- Guideline recommendations for allergic rhinitis and asthma have been updated since the original article was published, to incorporate the FDA's warning for montelukast

Montelukast Evaluation: Updates (cont.)

- Rhinitis 2020: A practice parameter update now recommends that clinicians 1) avoid leukotriene receptor antagonist (LTRAs), for treatment of nonallergic rhinitis and 2) reserve LRTAs for treatment of allergic rhinitis with inadequate response or intolerance to alternative therapies
- 2021 update of the Global Strategy for Asthma Management and Prevention list LRTAs as an alternative option for asthma management and encourage providers to weigh the risks of montelukast due to the FDA's Boxed Warning

Montelukast: Select Recommendations

- Research/Policy Recommendations:
  - Continue to monitor research and FDA communications regarding montelukast.
  - Continue to monitor the use of montelukast in the Medi-Cal population
- Board Recommendations:
  - None at this time

Board questions/recommendations?

Core Set Measures

- Care of Acute and Chronic Conditions
  - Asthma Medication Ratio: Ages 19 to 64 (AMR-AD)
  - Asthma Medication Ratio: Ages 5–18 (AMR-CH)
  - Comprehensive Diabetes Care: HbA1c Poor Control (>9.0%) (HPC-AD)
  - Controlling High Blood Pressure: Ages 18 to 85 (CBP-AD)
- FFY 2020 data published December 2021

Asthma Medication Ratio: Ages 19 to 64 (AMR-AD)

- Reports the percentage of adults ages 19 to 64 who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year
  - Higher rates are better on this measure
- 42 states voluntarily reported these data to CMS
- FFY 2020 rate include FFS and 25 MCOs, excludes duals
  - Rate was validated by the state's EQRO

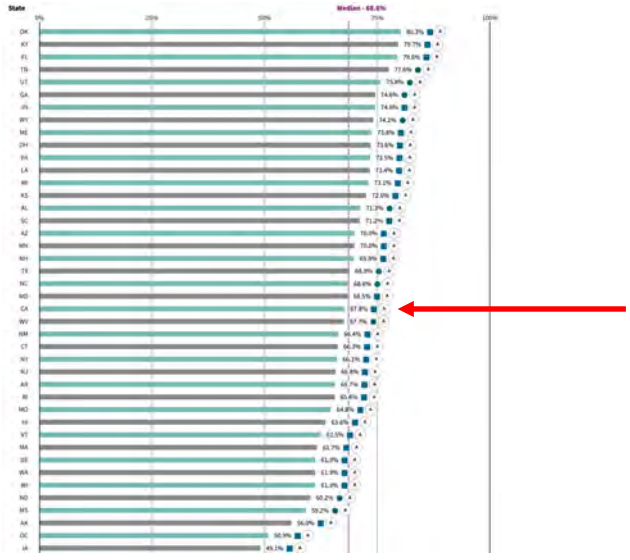
Asthma Medication Ratio: AMR-AD

- California = 55.1%
- Median = 53.7%
- Range = 71.3% (Oklahoma) to 24.2% (Iowa)

Asthma Medication Ratio: Ages 5–18 (AMR-CH)

- Reports the percentage of children and adolescents ages 5 to 18 who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year
  - Higher rates are better on this measure
- 43 states voluntarily reported these data to CMS
- FFY 2020 rate includes FFS and 25 MCOs
  - Managed care data were audited by the state's EQRO
  - State conducted an internal validation of FFS data

Asthma Medication Ratio: AMR-CH



- California = 67.8%
- Median = 68.5%
- Range = 80.3% (Oklahoma) to 49.1% (Iowa)

Control Asthma: Select Recommendations

- Asthma is one of six high-burden health conditions with effective interventions chosen for CDC's 6|18 Initiative
- Promote evidence-based asthma medical management described in the 2007 National Asthma Education and Prevention Program (NAEPP) guidelines
- Promote strategies that help people access and continue to use asthma medications and devices

Control Asthma: Select Recommendations (cont.)

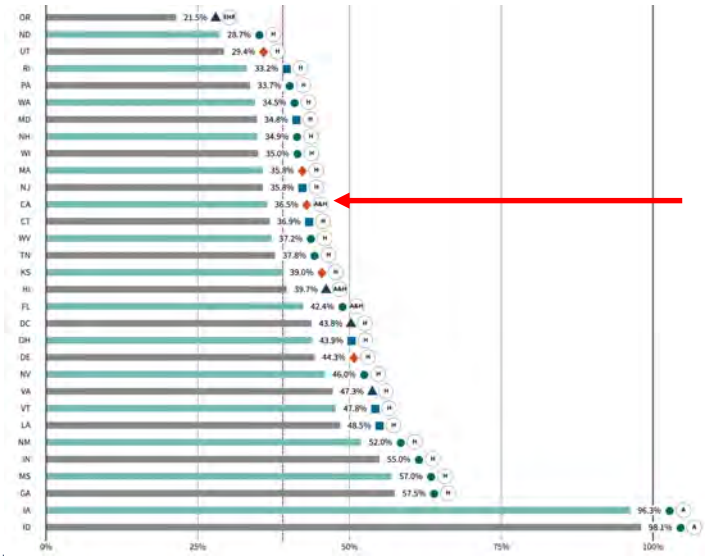
- Expand access to intensive self-management education for people whose asthma is not well controlled with guidelines-based medical management alone
- Make it easier for people with asthma to have home visits by licensed professionals or qualified lay health workers, if their asthma is not under control with medication and education

Board questions/recommendations?

Comprehensive Diabetes Care: HbA1c Poor Control (>9.0%) (HPC-AD)

- Reports the percentage of adults ages 18 to 75 with Type 1 or Type 2 diabetes who had HbA1c in poor control (>9.0%) during the measurement year
  - Lower rates are better on this measure
- 31 states voluntarily reported these data to CMS
- FFY 2020 rate includes 25 MCOs and duals, but excludes FFS and those not in MCO plan for duration of measurement year
  - 2 MCOs used administrative method and 23 used hybrid method
  - Rate was validated by the state's EQRO

Comprehensive Diabetes Care (HPC-AD)



- California = 36.5%
- Median = 39.0%
- Range = 21.5% (Oregon) to 98.1% (Idaho)

UCSF

Comprehensive Diabetes Care: Select Recommendations

- Use the Guiding Principles for the Care of People With or at Risk for Diabetes, which identifies areas of agreement among existing guidelines to help deliver care to adults who are at risk for or who have type 2 diabetes
- At every health care visit, primary care providers and all members of a patient's health care team should encourage them to take their medicines as prescribed and get regular care for their eyes, ears, feet, and teeth

UCSF

UCSF

Comprehensive Diabetes Care: Select Recommendations (cont.)

- Refer patients to or offer Diabetes Self-Management Education and Support (DSMES) Services
- Review the American Diabetes Association (ADA) 2022 Standards of Medical Care in Diabetes, which includes current clinical practice recommendations and is intended to provide clinicians, patients, researchers, payers, and others with the components of diabetes care, general treatment goals, and tools to evaluate the quality of care

Board questions/recommendations?

Controlling High Blood Pressure: Ages 18 to 85 (CBP-AD)

- Reports the percentage of adults ages 18 to 85 diagnosed with hypertension with adequately controlled blood pressure (less than 140/90 mm Hg) during the measurement year
  - Higher rates are better on this measure
- 33 states voluntarily reported these data to CMS
- FFY 2020 Rates include FFS and 25 MCOs, excludes duals
  - FFS and 2 MCOs used administrative method and 23 MCOs used hybrid method
  - Rate was validated by the state's EQRO

Controlling High Blood Pressure (CBP-AD)

- California = 61.1%
- Median = 59.2%
- Range = 73.7% (Utah) to 11.0% (Alabama)

Controlling High Blood Pressure: Select Recommendations

- Control of high blood pressure is one of six high-burden health conditions with effective interventions in CDC's 6|18 Initiative
- Improve adherence to anti-hypertensive and lipid-lowering prescription medications via expanded access to:
  - Fixed-dose medication combinations and extended medication fills
  - Innovative pharmacy packaging (e.g., calendar blister packs)
  - Improved care coordination using standardized protocols, primary care teams with pharmacists and community health workers, MTM programs, and self-monitoring of blood pressure with clinical support

Controlling High Blood Pressure: Select Recommendations (cont.)

- Provide home blood pressure monitors to patients with high blood pressure and reimburse clinicians for the clinical support services required for self-measured blood pressure monitoring (SMBP)

Board questions/recommendations?

UCSF

Future Topics: Retrospective Reviews

- Core Set Measures: Behavioral Health (September meeting)
- Baseline review of concomitant use of opioids/opioid agonists (September meeting)
- NSAIDs
- Pharmacist furnishing of hormonal contraceptives
- Assessment of opioid use and mortality (stratified by gender)
- Antipsychotic polypharmacy in adults
- SGLT2 inhibitors in patients without diabetes for heart failure

UCSF

Board questions/recommendations?

State of California
MEDICAID DRUG UTILIZATION REVIEW

Centers for Medicare & Medicaid Services
Federal Fiscal Year 2021

ANNUAL REPORT
FEDERAL FISCAL YEAR 2021

This report covers the period
October 1, 2020, to September 30, 2021

The Great Seal

Department of Health Care Services

Prepared by

Medi-Cal DUR

UCSF
University of California
San Francisco

Under the direction of the Medi-Cal Pharmacy Benefits Division
and the Global Medi-Cal Drug Use Review Board

Global Medi-Cal Drug Use Review Board
Federal Fiscal Year (FFY) 2021 Annual Report
October 1, 2020, to September 30, 2021

TABLE OF CONTENTS

I. DEMOGRAPHIC INFORMATION

State Name Abbreviation: CA
Medicaid Program Information: Identify state person responsible for DUR Annual Report Preparation:

Name: Ivana Thompson, PharmD
Email Address: Ivana.Thompson@dhcs.ca.gov
Area Code/Phone Number: (916) 345-8642

1. On a monthly average, how many of your state's Medicaid beneficiaries are enrolled in your state's Medicaid Fee-For-Service (FFS) program that have a pharmacy benefit? 2,307,558 Beneficiaries

2. On a monthly average, how many of your state's Medicaid beneficiaries are enrolled in managed care plan(s)? 11,439,224 Beneficiaries

II. PROSPECTIVE DUR (ProDUR)

1. Indicate the type of your pharmacy point of service (POS) vendor:
   - ☐ State-Operated
   - ☒ Contractor
   - ☐ Other

   a) Vendor Name: DXC Technology

   b) Who processes the state's National Council for Prescription Drug Programs (NCPDP) transactions?
      - ☒ POS is the fiscal agent (FA)
      - ☐ POS is a separate Pharmacy Benefits Manager (PBM)
      - ☐ None

2. Identify your ProDUR table driven criteria source. This would be initial ratings such as drug to drug interactions, dose limits based on age and pregnancy severity. Check **all** that apply.

   ☒ First Data Bank ☐ Medi-Span ☐ Micromedex ☐ Other

   If the answer above is "Other," please specify: _____

3. When the pharmacist receives a ProDUR alert message that requires a pharmacist's review, does your system allow the pharmacist to override the alert using the "NCPDP drug use evaluation codes" (reason for service, professional service, and resolution)?

   ☒ Yes ☐ Varies by alert type ☐ No

If "Yes" or "Varies by Alert Type," check **all** that apply.

☒ Alerts can be overridden ahead of time
☒ Alerts can be overridden with standard professional codes
☐ Alerts need prior authorization (PA) to be overridden
☐ Other, please explain: _____

4. Does your state receive periodic reports providing individual pharmacy providers DUR alert override activity in summary and/or in detail?

☒Yes ☐No

a) If the answer to (4) is "Yes," how often does your state receive reports?

☐ Monthly ☐ Quarterly ☒ Annually ☒ Ad hoc (on request) ☐ Other

If the answer above is "Other," please explain:
_____

b) If you receive reports, does your state follow-up with those providers who routinely override with interventions?

☒Yes ☐No

If the answer to (4b) above is "Yes," by what method does your state follow-up?
☒ Contact Pharmacy
☐ Refer to Program Integrity for Review
☐ Other, please explain.
_____

If the answer to (4b) above is "No," please explain why you do not follow-up with providers.
_____

5. Early Refill:

a) At what percent threshold does your state set your system to edit?

Non-controlled drugs: 75%
Schedule II Controlled drugs: 75%
Schedule III through V Controlled drugs: 75%

b) For non-controlled drugs:

When an early refill message occurs, does your state require a PA?

☐Yes ☒No ☐Dependent on medication or situation

If the answer to (5b) is "Yes" or "Dependent on medication or situation," who obtains authorization?

☐ Pharmacist ☐ Prescriber ☐ Either

If the answer to (5b) is "No," can the pharmacist override at the POS?

☒Yes ☐No

c) For controlled drugs:

When an early refill message occurs, does your state require a PA?

☐Yes ☒No

If the answer to (5c) is "Yes," who obtains authorization?

☐ Pharmacist ☐ Prescriber ☐ Either

If the answer to (5c) is "No," can the pharmacist override at the POS?

☒Yes ☐No

6. When the pharmacist receives an early refill DUR alert message that requires the pharmacist's review, does your state's policy allow the pharmacist to override for situations such as:

a) ☒ Lost/stolen Rx

b) ☒ Vacation

c) ☐ Overrides are only allowed by a pharmacist through a prior authorization

d) ☒ Other, please explain: The pharmacist can override the early refill DUR alert message for any situation if medically necessary.

7. Does your system have an accumulation edit to prevent patients from continuously filling prescriptions early?

☐Yes ☒No

a) If "Yes," please explain your edit.

_____

b) If "No," does your state plan to implement this edit? ☐Yes ☒No

8. Does the state Medicaid program have any policy prohibiting the auto-refill process that occurs at the POS (i.e., must obtain beneficiary's consent prior to enrolling in the auto-refill program)?

☐Yes ☒No

9. For drugs not on your Preferred Drug List (PDL), does your Medicaid program have a documented process (i.e., PA) in place, so that the Medicaid beneficiary or the Medicaid beneficiary's prescriber may access any covered outpatient drug when medically necessary?

☒Yes ☐No

If the answer to 9 is "Yes," please check **all** that apply:

☐ Automatic PA based on diagnosis codes or systematic review
☐ Trial and failure of first or second-line therapies
☐ Pharmacist or technician reviews
☐ Direct involvement with Pharmacy and/or Medical Director
☒ Other, please explain: The Medicaid beneficiary or the Medicaid beneficiary's prescriber may access any covered outpatient drug not on the Medi-Cal Fee-for-Service List of Contract Drugs (CDL) with an approved *Treatment Authorization Request.*

If the answer to 9 is "No," please explain.

_____

a) Does your program provide for the dispensing of at least a 72-hour supply of a covered outpatient drugs (COD) in an emergency situation?

☒Yes ☐No

If the answer to (9a) is "Yes," please check **all** that apply:

☐ Real-time automated process
☐ Retrospective PA
☒ Other process, please explain: The pharmacy may manually bill a 72-hour supply of a covered outpatient prescription drug in an emergency situation.

If the answer to (9a) is "No," please explain:

_____

10. Please list the requested data in each category in **Table 1- Top Drug Claims Data Reviewed by the DUR Board** below.

Table 1: Top Drug Claims Data Reviewed by the DUR Board

Top 10 PA Requests by Drug Name	Top 10 PA Requests by Drug Class	Top 5 Claim Denial Reasons (i.e. QL, Early Refill, PA, Duplication)	Top 10 Drug Names by Amount Paid	% of Total Spent for Drugs by Amount Paid	Top 10 Drug Names by Claim Count	Drugs By Claim Count % of Total Claims
aripiprazole	antipsychotic agents	PA required	bictegravir/emtricitabine/ tenofovir alafenamide	10.0%	COVID-19 vaccine (Pfizer)	11.0%
paliperidone	analgesics, narcotic agents	age	lurasidone	6.8%	COVID-19 vaccine (Moderna)	5.0%
risperidone	dietary supplements, misc.	quantity dispensed exceeds maximum allowed	paliperidone	6.6%	quetiapine fumarate	4.9%
quetiapine	infant formulas	exceeds allowable plan days supply	aripiprazole	3.1%	aripiprazole	3.8%
cariprazine	anticonvulsant agents	m/i diagnosis code	emicizumab-kxwh	2.8%	olanzapine	3.1%
brexpiprazole	stimulants and related agents	XXXXXXX	elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide	2.4%	risperidone	2.8%
haloperidol	bipolar disorder drugs	XXXXXXX	emtricitabine/tenofovir alafenamide	2.3%	ibuprofen	1.9%
hydrocodone/ acetaminophen	vitamin agents	XXXXXXX	abacavir/ dolutegravir/ lamivudine	2.2%	benztropine mesylate	1.8%
buprenorphine	benzodiazepines	XXXXXXX	antihemophilic factor, FVIII, full length	2.0%	buprenorphine HCl/naloxone HCl	1.7%
olanzapine	adrenergics, aromatic, non-cate	XXXXXXX	coagulation factor VIIa (recombinant)	2.0%	metformin	1.6%

11. Section 1927(g)(A) of the Social Security Act (the Act) requires that the pharmacist offer patient counseling at the time of dispensing. Who in your state has responsibility for monitoring compliance with the oral counseling requirement? Check **all** that apply:

☐ Medicaid Program
☒ State Board of Pharmacy
☐ Other, please explain: _____

III. RETROSPECTIVE DUR (RetroDUR)

1. Indicate the type of vendor that performed your RetroDUR activities during the time period covered by this report:

   ☐ Company ☒ Academic institution ☐ Other organization

   a) Identify, by name, your RetroDUR vendor: University of California, San Francisco (UCSF)

   b) Is the RetroDUR vendor the Medicaid Management Information System (MMIS) fiscal agent?

   ☐Yes ☒No

   c) Is the RetroDUR vendor also the developer/supplier of your retrospective DUR criteria?

   ☐Yes ☒No

   Please explain "Yes" or "No" response: Retrospective DUR criteria are developed jointly by UCSF and DHCS with input and recommendation by the DUR board. Final approval of criteria is made by DHCS.

   d) Does your state customize your RetroDUR vendor criteria?

   ☒Yes ☐No ☐Ad-hoc based on state-specific needs

2. How often does your state perform retrospective practitioner-based education?
   ☐ Monthly
   ☐ Bi-monthly
   ☐ Quarterly
   ☒ Other, please specify: Practitioner-based education is performed at least on a quarterly basis and more frequently as needed.

   a) How often does your state perform retrospective reviews that involve communication of client specific information to healthcare practitioners (through messaging, fax, or mail)?
      ☐ Monthly
      ☐ Bi-monthly
      ☐ Quarterly
      ☒ Other, please specify: Retrospective reviews that involve communication of client specific information to healthcare practitioners are performed at least on a quarterly basis and more frequently as needed.

b) What is the preferred mode of communication when performing RetroDUR initiatives? Check **all** that apply.
- ☒ Mailed letters
- ☐ Provider phone calls
- ☐ Near real-time fax
- ☐ Near real-time messaging
- ☐ Other new technologies such as apps or Quick Response (QR) codes
- ☐ Focused workshops, case management, or WebEx training
- ☒ Newsletters or other non-direct provider communications
- ☐ Other, please specify: _____

3. **Summary 1 – RetroDUR Educational Outreach Summary**
Summary 1: RetroDUR Educational Outreach is a year-end summary report on retrospective screening and educational interventions. The year-end summary should be limited to the most prominent problems with the largest number of exceptions. The results of RetroDUR screening and interventions should be included and detailed below.

1. Benzodiazepines
   - o Educational alert published October 2020 – This alert was published in response to a U.S. Food and Drug Administration (FDA) announcement that required the *Boxed Warning* for all benzodiazepines to be updated to reflect the serious risks of abuse, misuse, addiction, physical dependence, and withdrawal reactions.
   - o Clinical Review: Recommendations for the Tapering of Benzodiazepines published March 2021 – This bulletin reviewed the risks of dependence and withdrawal during benzodiazepine therapy and discussed strategies for designing a safe taper.
   - o Provider letter sent April 2021 – The objective was to inform health care providers about safety issues associated with benzodiazepine tapering. A total of 153 letters were mailed on April 18, 2021, to the top prescribers of benzodiazepines (by total paid claims) in the Medi-Cal program. Each prescriber was sent a letter that included the Medi-Cal DUR bulletin on benzodiazepine tapering and a provider survey.

2. Management of Acute Dental Pain
   - o Educational bulletin published January 2021 – This bulletin reviewed recommendations from the American Dental Association (ADA) and the American Academy of Pediatric Dentistry (AAPD) regarding routine management for acute dental pain, including the recommendations for non-opioid analgesics as first line agents.
   - o Provider letter sent February 2021 – The objective was to inform dentists about the updated American Dental Association (ADA) and the American Academy of Pediatric Dentistry (AAPD) recommendations for the management of acute dental pain. Letters were mailed on February 16, 2021, to the top 153 dentists by total –paid claims for opioid medication exceeding a three-day supply

between March 1, 2019, and February 29, 2020. Each prescriber was sent a letter that included the Medi-Cal DUR bulletin on management of acute dental pain and a provider survey.

3. Potential Increased Arrhythmia Risk from Lamotrigine
   - Educational alert published April 2021 – This alert was published in response to the FDA's Drug Safety Communication that discussed the potential for Increased risk of arrythmias with use of lamotrigine and summarized recommendations for patients that are continued on lamotrigine therapy.

4. Pregnancy Contraindication Removed for Statins
   - Educational alert published August 2021 – This alert was published in response to the FDA's request to remove the contraindication against using statin medications in people who are pregnant and recommendation to continue therapy in pregnant patients at very high risk of cardiovascular events.
   - Provider letter sent September 2021 – The objective was to inform health care providers about the FDA announcement that it is requesting removal of its strongest warning against using cholesterol-lowering statin medicines in pregnant patients. Letters were mailed on September 20, 2021, to the top 200 prescribers of statins to female Medi-Cal FFS beneficiaries between 15 and 49 years of age during 2021. Each prescriber was sent a letter that included the Medi-Cal DUR alert and a provider survey.

5. Voluntary Recall of Varenicline (Chantix) Due to Nitrosamine
   - Educational alert published August 2021 and updated September 2021 – This alert was published in response to the FDA's Drug Safety Communication that announced a voluntary manufacturer recall of varenicline tablets due to levels of nitrosamine impurity above the FDA's acceptable limit and recommended patients continue taking recalled varenicline until a replacement is provided.
   - Provider letter sent October 2021 – The objective was to inform health care providers about a voluntary manufacturer recall of all lots of varenicline (Chantix) 0.5 mg and 1 mg tablets due to unacceptable levels of a nitrosamine impurity, called N-nitroso-varenicline. The letter was sent to the top 200 prescribers of varenicline to Medi-Cal beneficiaries since January 1, 2021. Each prescriber received a letter that includes the updated Medi-Cal DUR alert on the varenicline recall and a provider survey.

6. 2020 Immunization Updates: Vaccination during COVID-19, Flu, HepA, and Tdap
   - Educational bulletin published September 2021 – This bulletin is an annual publication provided by the DUR program to provide updates on immunization guidelines, products, policy and/or research each year. Links to recommended immunization schedules for 2021 in the United States were also provided. The summary for 2021 included updates for COVID-19 vaccines, influenza vaccine, Hepatitis A (HepA) vaccine, tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine, as well as a review of strategies to improve COVID-19 vaccination rates.

IV. DUR BOARD ACTIVITY

1. Does your state have an approved Medication Therapy Management (MTM) Program?

☒Yes ☐No

2. **Summary 2 – DUR Board Activities Summary**

Summary 2: DUR Board Activities Summary should be a brief descriptive report on DUR Board activities during the fiscal year reported. Please provide a summary below:

- Indicate the number of DUR Board meetings held.
- List additions/deletions to DUR Board approved criteria.
  a. For prospective DUR, list problem type/drug combinations added or deleted.
  b. For retrospective DUR, list therapeutic categories added or deleted.
- Describe Board policies that establish whether and how results of ProDUR screening are used to adjust retrospective DUR screens.
- Describe policies that establish whether and how results of RetroDUR screening are used to adjust ProDUR screens.
- Describe DUR Board involvement in the DUR education program (i.e., newsletters, continuing education, etc.).
- Describe policies adopted to determine mix of patient or provider specific intervention types (i.e., letters, face-to-face visits, increased monitoring).

The DUR Board met four times during FFY 2021. Due to the coronavirus disease 2019 (COVID-19) pandemic, the meetings were abbreviated, webinar-only meetings.

Prospective DUR Criteria Presented

- Review of new Generic Code Number (GCN) sequence numbers: The DUR Board recommended turning on additional alerts for 31 new GCNs that matched drugs appearing on the Medi-Cal target drug list for prospective DUR.

Retrospective DUR Criteria Presented

- Review of Retrospective DUR Criteria: New Additions to the Medi-Cal List of Contract Drugs in FFY 2019 – During FFY 2019 there were a total of 26 new prescription medications added to the Medi-Cal List of Contract Drugs. Utilization data (total number of paid claims and utilizing beneficiaries with at least one paid claim) were reviewed for each of these drugs. Twenty drugs had low utilization (< 20 utilizing beneficiaries during all of the months reviewed) and were not reported in detail. The Board did not suggest additional evaluation for any of these drugs.

- Psychotropic Medication Use in Children and Adolescents – An evaluation was conducted that reviewed all psychotropic medication use over time among children and adolescents under 18 years of age, not just antipsychotic medications. In addition, this evaluation aimed to determine if use of psychotropic medications in

children and adolescents is different when stratified by children in foster care compared with children not in foster care and those enrolled in the Medi-Cal FFS program compared with children enrolled in a Medi-Cal managed care plan. Utilizing beneficiaries with a paid claim for any psychotropic medication has been in decline since 2013Q1. All classes of psychotropic medications continue to decrease over time and there appears to be no replacement with other medication classes after an initial decrease in paid claims for antipsychotic medications and no curve back to pre-policy use levels of antipsychotic medications was observed. It was noted that COVID-19 may have decreased paid claims for stimulants due to distance learning. Continued monitoring of the use of psychotropic medications within the Medi-Cal population younger than 18 years of age was recommended, with particular attention to stimulants as distance learning continues. Additionally, it was recommended to assess the impact of the transition on utilization of these drugs (and similar classes) that had been previously carved out after implementation of Medi-Cal Rx on January 1, 2022.

- Hepatitis C Virus (HCV) Drugs – Paid claims for HCV medications with dates of service between October 1, 2019, and September 30, 2020 (FFY 2020), in both the Medi-Cal FFS and MCP population, were reviewed. This evaluation included the number of beneficiaries with a diagnosis code indicating HCV infection, the total number of beneficiaries initiating treatment for HCV infection, and regional stratification of these data to identify potential areas in the state that may benefit from additional outreach. The results showed that regional variation in treatment ranged from low of 4.9% (FFS in Fresno region) to high of 17.6% (FFS in San Diego region). In addition, a total of 7,111 beneficiaries were identified as having a paid claim for an HCV medication, which was a decrease from 2019 in both FFS (decrease of 15%) and managed care (27%). There were not any obvious areas requiring intervention and glecaprevir/pibrentasvir and sofosbuvir/velpatasvir continue to be the top medications by total utilizing beneficiaries. As baseline HCV-RNA level and comprehensive metabolic panel are required before initiating treatment, prescribing trends remain in line with guidelines, and there is continued limited evidence of retreatment over time. The Board requested this stratified analysis be completed for one additional year.

- Opioid use in Emergency Departments – An evaluation was conducted on opioid prescribing practices in the emergency department (ED). All paid outpatient pharmacy claims for opioids were reviewed with dates of service between January 1, 2021, and June 30, 2021. Any pharmacy claims were included if prescribers had taxonomy codes, specialty codes, or practice locations indicating emergency medicine. Primary outcomes included the percentage of patients receiving greater than a 3-day supply of opioids (33.5%) and the percentage of patients receiving greater than a 7-day supply of opioids (10.3%). Less than ten beneficiaries had cumulative paid claims for opioids greater than 80 morphine milligram equivalent (MME)/day and that most beneficiaries (82%) had only one opioid paid claim from an ED prescriber during the 6-month period. Most claims (93%) were for ≤ 7 days' supply or less, although a small percentage of beneficiaries had more than one

claim for ≤ 7 days. Among children and adolescents, of the 118 beneficiaries under 18 years of age with a paid claim for an opioid medication, only 36% of beneficiaries had greater than a 3-day supply of opioids and only 8% had greater than a 7-day supply of opioids.

- Opioid use among Dentists – Current opioid prescribing practices by dentists and oral surgeons were evaluated in the Medi-Cal program. All paid outpatient pharmacy claims for opioids were reviewed with dates of service between January 1, 2021, and June 30, 2021. Any pharmacy claims were included if prescribers had taxonomy codes or specialty codes indicating they were dentists or oral surgeons. Primary outcomes included the percentage of patients receiving greater than a 3-day supply of opioids (66.2%) and the percentage of patients receiving greater than a 7-day supply of opioids (13.8%). Approximately 63% of paid claims were for acetaminophen w/codeine, with the majority (97%) for ≤ 7 days' supply and the most common paid claim for a 5 days' supply (26%) or 20 tablets (29%). In addition, 32% of paid claims were for hydrocodone w/acetaminophen, with the majority (97%) for ≤ 7 days' supply and the most common paid claim was for a 3 days' supply (25%) or 20 tablets (27%). There were no paid claims for greater than 80 MME/day and 82% of utilizing beneficiaries had only one paid claim for an opioid during the measurement period.

- Opioid use in Outpatient Surgical Settings – Current opioid prescribing practices for acute pain management following common, low-risk outpatient surgical procedures were evaluated. All paid outpatient pharmacy claims for opioids were reviewed for eligible beneficiaries between 18 and 64 years of age with dates of service between January 1, 2021, and June 30, 2021. Any pharmacy claims were included if prescribed up to three days after one of the following low-risk outpatient procedures where opioids are typically prescribed as a first-line therapy for acute pain:
  - Laparoscopic cholecystectomy (CPTs: 47562, 47563, and 47564)
  - Laparoscopic inguinal hernia (CPTs: 49650 and 49651)
  - Laparoscopic appendectomy (CPT: 44970)
  - Knee arthroscopy with meniscectomy (CPTs: 29880 and 29881)
  - Partial excision of breast (CPTs: 19301, 19302, and 19120)

  Outcomes included the proportion of patients with a paid claim for an opioid prescription within three days following procedure date (ranged from 51.6% to 60.2%), the percentage of patients with a daily opioid dose prescribed greater than 80 morphine milligram equivalents (ranged from 0% to < 1.0%), the percentage of patients receiving greater than a 3-day supply of opioids (ranged from 29.4% to 81.1%), and the percentage of patients receiving greater than a 7-day supply of opioids (ranged from 1.1% to 13.2%). Paid claims for opioids prescribed after common outpatient surgeries appeared appropriate and followed prescribing guidelines for acute pain and found no differences in prescribing or outcomes between FFS and MCP enrollees. Further, all procedures evaluated averaged less than 30 MME/day and that data limitations on OTC paid claims make it difficult to

evaluate utilization and prescribing patterns of other treatment options for acute pain management.

DUR Board Involvement in Provider-specific Interventions: The DUR Board advises and makes recommendations for educational articles, alerts, and provider intervention letters. The Board chair may appoint a Board member with subject matter expertise to perform a focused review, as appropriate.

Educational articles and alerts:

- Drug Safety Communication: Stronger Warning Labels for Benzodiazepines
- Clinical Review: Recommendations for the Management of Acute Dental Pain
- Clinical Review: Recommendations for the Tapering of Benzodiazepines
- Drug Safety Communication: Potential Increased Arrhythmia Risk from Lamotrigine
- Drug Safety Communication: FDA Requests Removal of Pregnancy Contraindication for Statins
- UPDATED: Drug Safety Communication: Voluntary Recall of Varenicline (Chantix) Due to Nitrosamine
- 2021 Immunization Updates: COVID-19, Influenza, and Meningococcal Disease

Provider intervention letters:

- Dentists and Opioids Letter – February 2021
- Benzodiazepine Letter – April 2021
- Statins in Pregnancy Letter – September 2021
- Varenicline Recall Letter – September 2021

Ongoing DUR Board projects:

The DUR Board goals for FFY 2021 were as follows:

- Support DHCS Medi-Cal Rx initiative
- Continue to promote dialogue, collaboration among MCOs
  - Present innovative practices and projects
  - Share approaches and lessons learned
  - Disseminate DUR educational bulletins to MCPs
  - Integrate/align FFS and MCO DUR action items
- Align goals with DHCS Comprehensive Quality Strategy
- Align goals with California Advancing and Innovating Medi-Cal (CalAIM)
- Revisit Healthcare Effectiveness Data and Information Set (HEDIS) measures
- Continue to use the Vital Directions Framework to focus on the three DUR priority areas:
  - Optimizing drug prescribing and dispensing, including specialty drugs
  - Optimizing pain management and opioid use
  - Optimizing medication management, prevention, and wellness for chronic conditions, with a special focus on diabetes, hypertension, depression, and anxiety

V. PHYSICIAN ADMINISTERED DRUGS

The Deficit Reduction Act required collection of national drug code (NDC) numbers for covered outpatient physician administered drugs. These drugs are paid through the physician and hospital programs. Has your MMIS been designed to incorporate this data into your DUR criteria for:

1. ProDUR?

☐Yes ☒No

If "No," does your state have a plan to include this information in your DUR criteria in the future?

☐Yes ☒No

2. RetroDUR?

☒Yes ☐No

If "No," does your state have a plan to include this information in your DUR criteria in the future?

☐Yes ☐No

VI. GENERIC POLICY AND UTILIZATION DATA

Summary 3 – Generic Drug Substitution Policies
Summary 3 Generic Drug Substitution Policies should summarize factors that could affect your generic utilization percentage. In describing these factors, please explain any formulary management or cost containment measures, preferred drug list (PDL) policies, educational initiatives, technology or promotional factors, or other state specific factors that affects your generic utilization rate.

Among possible factors contributing to the Medi-Cal fee-for-service generic utilization percentage, the most impactful are the following: 1) supplemental rebate contracts with manufacturers; 2) carve-out drugs; and 3) generic drug pricing policies.

1) Restrictions to the Medi-Cal List of Contract Drugs

The Medi-Cal Drug Rebate program negotiates supplemental rebate contracts with pharmaceutical manufacturers and collects rebates greater than rebates obtainable through federal contracts alone. As a result, the net cost to the State for some brand name drugs can be lower than the therapeutically equivalent generic drug. In some cases, contracted drugs are payable at the point of service, while their generic equivalents

require prior authorization. On the Medi-Cal List of Contract Drugs, these drugs can be identified through restrictions to the NDC labeler code.

2) Carve-out Pharmacy Benefits

The Medi-Cal fee-for-service program pays for certain carved-out therapeutic classes of drugs for beneficiaries in both the Medi-Cal fee-for-service program and the Medi-Cal managed care program. Most notably, this applies to selected psychiatric drugs, alcohol and heroin detoxification and dependency treatment drugs, coagulation factors, and drugs used in treatment of Human Immunodeficiency Virus (HIV) and AIDS. These classes of drugs are largely single-source innovator products and consistently account for a large portion of Medi-Cal drug benefit expenditures in the Medi-Cal fee-for-service population.

3) Policies encouraging generic equivalent substitution for drugs dispensed through the Medi-Cal program.

In cases where generic drugs are more cost-effective, Medi-Cal encourages use of generic drugs. The providers, to the extent permitted by law, shall dispense the lowest cost drug product within the generic drug type in stock, which meets the medical needs of the beneficiary.

Reimbursement for any legend and non-legend drug covered under the Medi- Cal program is the lowest of:

1. Actual acquisition cost (AAC) plus a professional dispensing fee. The AAC is equal to the lowest of the following:
   - National Average Drug Acquisition Cost (NADAC), or when no NADAC is available, the wholesale acquisition cost (WAC)
   - Maximum Allowable Ingredient Cost (MAIC)
   - Federal Upper Limit (FUL)
2. The pharmacy's usual and customary charge.

Among these, whenever available, MAIC and FUL promote the use of generic equivalents unless restricted on the Medi-Cal List of Contract Drugs. The rates established by MAIC or FUL are generally much lower than the cost of branded products, which discourages providers from filling prescriptions with name brand drugs. Full reimbursement of prescription ingredient cost requires use of a brand of a multiple source drug, which costs no more than the program specified price limits. When medically necessary for a specific recipient, approval of reimbursement may be obtained for a product whose price exceeds the MAIC or FUL price limits by requesting authorization from a Medi-Cal consultant.

National Average Drug Acquisition Cost (NADAC)

The National Average Drug Acquisition Cost (NADAC) is used as the basis for the actual acquisition cost-based ingredient cost reimbursement for covered outpatient drugs. The NADAC is a national drug-pricing benchmark determined by a federal survey, representing the national average invoice price for drug products based on invoices from wholesalers and manufacturers submitted by retail community pharmacies. Wholesale acquisition cost (WAC) plus 0 percent is used as the basis for reimbursement when a

NADAC is not available. The methodology reimburses the lower of the NADAC, WAC, federal upper limit (FUL), maximum allowable ingredient cost (MAIC) or the pharmacy's usual and customary charge.

Maximum Allowable Ingredient Cost (MAIC)
The Maximum Allowable Ingredient Cost (MAIC) program establishes maximum ingredient cost limits for generically equivalent drugs. Each cost limit is established only when there are three or more generically equivalent drugs available for purchase and dispensing by retail pharmacies within California.

Federal Upper Limit (FUL)
Federal Upper Limit (FUL) is an upper limit of reimbursement for certain multiple source drugs established independently from the California MAIC Program by the United States Department of Health and Human Services (DHHS). The federally required FUL is administered by the Medi-Cal program in a similar manner as the MAIC program. The major difference is that changes to the FUL list of drugs and respective price limits are issued periodically by DHHS and then implemented by Medi-Cal. When a drug is listed on both the MAIC and FUL price lists, the reimbursement rate is the lower of the MAIC or FUL.

1. In addition to the requirement that the prescriber write in his own handwriting "Brand Medically Necessary" for a brand name drug to be dispensed in lieu of the generic equivalent, does your state have a more restrictive requirement?

   ☒Yes ☐No

   If "Yes", check all that apply:

   a) ☐ Require that a MedWatch Form be submitted
   b) ☐ Require medical reason(s) for override accompanying the prescription(s)
   c) ☐ Prior authorization (PA) is required
   d) ☒ Other, please explain: If a brand name drug does not appear on the Medi-Cal List of Contract Drugs, an approved *Treatment Authorization Request* demonstrating medical necessity may be required before dispensing.

   Please provide the following utilization data for this DUR reporting period for all covered outpatient drugs paid. Exclude Third Party Liability (TPL).

Table 2: Generic Drug Utilization Data

	Single Source (S) Drugs	Non-Innovator (N) Drugs	Innovator Multi-Source (I) Drugs
Total Number of Claims	1,005,206	6,040,489	366,635
Total Reimbursement Amount Less Co-Pay	$2,496,227,995	$161,891,085	$166,304,379

2. Indicate the generic utilization percentage for all covered outpatient drugs (COD) paid during this reporting period, using the computation instructions in **Table 2 – Generic Drug Utilization Data**.

Number of Generic Claims:	6,040,489
Total Number of Claims:	7,412,330
Generic Utilization Percentage:	81.49%

3. How many innovator drugs are the preferred product on your state PDL when multi-source drugs are available based on net pricing and rebates (i.e. brand preferred over generic)? __55__

4. Indicate the percentage dollars paid for generic CODs in relation to all COD claims paid during this reporting period using the computation instructions in **Table 2 - Generic Utilization Data**.

Generic Dollars:	$161,891,085
Total Dollars:	$2,824,423,459
Generic Expenditure Percentage:	5.73%

5. Does your state have any policies related to Biosimilars? Please explain:

   No, there is not a special state policy unique to Biosimilars.

VII. PROGRAM EVALUATION/COST SAVINGS/COST AVOIDANCE

1. Did your state conduct a DUR program evaluation of the estimated cost savings/cost avoidance?

   ☒Yes ☐No

   If "Yes," identify, by name and type, the institution that conducted the program evaluation.

   ☐ Company ☒ Academic Institution ☐ Other Institution

   Institution name: University of California, San Francisco (UCSF)

2. Please provide your ProDUR and RetroDUR program cost savings/cost avoidance in the chart below.

ProDUR Total Estimated Avoided Costs	$168,043,939
RetroDUR Total Estimated Avoided Costs	$0
Other Cost Avoidance	$0
Grand Total Estimated Avoided Costs	**$168,043,939**

3. The Estimated Percent Impact was generated by dividing the Grand Total Estimated Avoided Costs from Question 2 above by the Total Dollar Amount provided in Section VI, Question 5, then multiplying this value by 100.

   Estimated Percent Impact = **5.94%**

4. **Summary 4 – Cost Savings/Cost Avoidance Methodology**
   Summary 4 Cost Savings/Cost Avoidance Methodology includes program evaluations/cost savings estimates prepared by state or contractor. Please provide detailed summary below.

   Prospective DUR alerts and educational bulletins provide health care providers and pharmacists with specific, focused, and comprehensive drug information. If DUR alerts and educational bulletins are reviewed as intended, then notification of a potential drug therapy problem through a DUR alert or the knowledge gained from educational bulletins will lead to appropriate action, including:
   - Discontinuing unnecessary prescriptions
   - Reducing quantities of medications prescribed
   - Switching to safer drug therapies
   - Adding a drug therapy recommended in evidence-based guidelines
   - Appropriate monitoring of patients taking prescription drugs

   The Medi-Cal DUR program has saved money by encouraging appropriate drug therapy in order to reduce total healthcare expenditures. Estimated prescription drug savings as a direct result of the prospective DUR system for FFY 2021 are shown below.

Prospective DUR Cost-Savings for Federal Fiscal Year (FFY) 2021.

Prospective DUR alert	Total claims cancelled or not overridden[1]	Average reimbursement dollars paid to pharmacies per claim[2]	Multiplier[3]	Total estimated costs avoided through prospective DUR
Over Utilization (Early Refill)	857,114	$451	0.1	$38,655,841
Therapeutic Duplication	345,573	$243	0.8	$67,179,391
Ingredient Duplication	260,299	$183	0.8	$38,107,774
Under Utilization (Late Refill)	87,905	$191	0.8	$13,431,884
Additive Toxicity	43,280	$86	0.8	$2,977,664
High Dose	42,271	$136	0.8	$4,599,085
Drug-Pregnancy	18,891	$64	0.8	$967,219
Low Dose	13,537	$165	0.8	$1,786,884
Drug-Drug Interaction	3,360	$59	0.8	$158,592
Drug-Disease Contraindication	2,671	$64	0.8	$136,755
Drug Age	474	$86	0.8	$32,611
Drug Allergy	158	$81	0.8	$10,238
TOTAL: All Alerts	***1,675,533***	***$210***		***$168,043,939***

[1]Multiple alerts can be generated per claim, so there may be duplicate alerts cancelled or overridden.

[2]Average reimbursement dollars paid to pharmacies per claim was calculated for each alert by looking at the total number of paid claims (including overrides) and total reimbursement dollars paid to pharmacies per claim (does not include adjustment for any rebates) for all drugs that generated that particular alert in FFY 2021.

[3]The use of this multiplier allows for an adjustment of estimated costs using a conservative estimate that 90% of early refill claims are resubmitted and paid and that 20% of the remaining alerts are duplicate alerts for the same claim.

VIII. FRAUD, WASTE, AND ABUSE DETECTION

A. LOCK-IN or PATIENT REVIEW AND RESTRICTIVE PROGRAMS

1. Does your state have a documented process in place that identifies potential fraud or abuse of controlled drugs by **beneficiaries**?

☒Yes ☐No

If "Yes," what action(s) does this process initiate? Check all that apply.
☐ Deny claims
☐ Require prior authorization (PA)
☐ Refer to Lock-In Program
☐ Refer to Program Integrity Unit and/or Surveillance Utilization Review (SUR) Unit for audit/investigation
☐ Refer to Office of Inspector General (OIG)
☒ Other, please explain:

22CCR §50793 details available utilization restrictions when the Department has determined that a beneficiary is misusing or abusing Medi-Cal benefits, including being subjected to one or more of the following forms of utilization restriction:
(1) Prior authorization for all Medi-Cal services.
(2) Prior authorization for specific Medi-Cal services.
(3) Restriction to utilization of a specific, beneficiary- or Department-selected pharmacy.
(4) Restriction to a specific, beneficiary- or Department-selected primary provider of medical services.

Audit & Investigations, Medical Review Branch (MRB), Special Investigative Unit (SIU) or Investigations Branch (IB) is responsible for working potential fraud or abuse of controlled drugs by beneficiaries. MRB, SIU, and IB has an intake process for complaints which entails an initial case review and if warranted, assignment of a case to an investigator/auditor. Subsequent actions are dependent upon the outcome of the investigation, which looks at claims data and trends.

2. Does your state have a Lock-In program for beneficiaries with potential misuse or abuse of controlled substances?

☐Yes ☒No

a) If "Yes", what criteria does your state use to identify candidates for Lock-In? Check **all** that apply:
☐ Number of controlled substances (CS)
☐ Different prescribers of CS
☐ Multiple pharmacies
☐ Days' supply of CS

☐ Exclusivity of short acting (SA) opioids
☐ Multiple emergency room (ER) visits
☐ Prescription Drug Monitoring Program (PDMP) data
☐ Other, please explain: _____

b) If "Yes" do you have the capability to restrict the beneficiary to:

- prescriber only ☐Yes ☐No
- pharmacy only ☐Yes ☐No
- prescriber and pharmacy ☐Yes ☐No

c) If the answer to (number 2) above is "Yes," what is the usual Lock-In time period?

☐ 12 months
☐ 18 months
☐ 24 months
☐ As determined by the state on a case-by-case basis
☐ Lock-in time period is based on the number of offences
☐ Other, please explain: _____

d) If the answer to (number 2) above is "Yes," on average, what percentage of the FFS population is in lock-in status annually? _____%

e) If the answer to (number 2) above is "Yes," please provide an estimate of the savings attributed to the Lock-In program for the fiscal year under review. $_____

3. Does your state have a documented process in place that identifies possible FWA of controlled drugs by **prescribers**?

☒Yes ☐No

If "Yes," what actions does this process initiate? Check **all** that apply.

☒ Deny claims written by this prescriber
☒ Refer to Program Integrity Unit (PIU) and/or Surveillance Utilization Review (SUR) Unit for audit/investigation
☐ Refer to the appropriate Medical Board
☒ Other, please explain: Audit & Investigations, Medical Review Branch (MRB), Special Investigative Unit (SIU) or Investigations Branch (IB) is responsible for working cases involving possible fraud or abuse of controlled drugs by prescribers. MRB, SIU, and IB has an intake process for complaints that entails an initial case review and – if warranted – assignment of a case to an investigator/auditor.

Subsequent actions are dependent upon the outcome of the investigation, which looks at claims data and prescribing trends. Current utilization controls include suspended provider lists, provider sanctions for a specified time period, provider sanctions from prescribing select medications, contracted drug list compliance,

code 1 restrictions, treatment authorization requests, maximum dispensing quantity restrictions, and maximum dispensing restrictions during a specified time period.

If the answer to (3) is "No," please explain: _____

4. Does your state have a documented process in place that identifies potential FWA of controlled drugs by **pharmacy providers**?

☒Yes ☐No

If "Yes," what actions does this process initiate? Check **all** that apply.
☒ Deny claim
☒ Refer to Program Integrity Unit and/or Surveillance Utilization Review (SUR) Unit for audit/investigation
☐ Refer to Board of Pharmacy
☒ Other, please explain: Audit & Investigations, Medical Review Branch (MRB), Special Investigative Unit (SIU) or Investigations Branch (IB) is responsible for working cases involving potential fraud or abuse of controlled drugs by pharmacy providers. MRB, SIU, and IB has an intake process for complaints that entails an initial case review and – if warranted – assignment of a case to an investigator/auditor.

Subsequent actions are dependent upon the outcome of the investigation, which looks at claims data and pharmacy dispensing trends. Current utilization controls include suspended pharmacy provider lists, restrictions placed upon individual pharmacist licenses by the State Board of Pharmacy, contracted drug list compliance, code 1 restrictions documentation, treatment authorization requests, maximum dispensing quantity restrictions, and maximum dispensing restrictions during a specified time period.

If the answer to (4) is "No," please explain: _____

5. Does your state have a documented process in place that identifies and/or prevents potential FWA of non-controlled drugs by **prescribers, pharmacy providers and beneficiaries**?

☒Yes ☐No

If "Yes," please explain your program for FWA of non-controlled substances: Audit & Investigations, Medical Review Branch (MRB), Special Investigative Unit (SIU) or Investigations Branch (IB) is responsible for working potential fraud or abuse of non-controlled drugs by beneficiaries. MRB, SIU, and IB has an intake process for complaints that entails an initial case review and – if warranted – assignment of a case to an investigator/auditor. Subsequent actions are dependent upon the outcome of the investigation, which looks at claims data and trends.

If the answer to (5) is "No," please explain: _____

B. PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

Note: *Section 5042 of the SUPPORT for Patients and Communities Act requires states to report metrics in reference to their state's PDMP. CMS has included questions to reference these metrics to help your state establish processes to be in compliance with provisions outlined in Section 5042 and CMS reporting, beginning in FFY 2023. Please complete applicable questions below in this section of the survey.*

1. Does your Medicaid program have the ability to query the state's PDMP database?

☐Yes, receive PDMP data
- ☐Daily
- ☐Weekly
- ☐Monthly
- ☐Other: _____

☐Yes, have direct access to the database
- ☐Can query by client
- ☐Can query prescriber
- ☐Can query by dispensing entity

☒No, please explain: California state law does not allow access to client data for this type of analysis.

a) If the answer to (number 1) above is "Yes", please explain how the state applies this information to control FWA of controlled substances:

b) If the answer to (number 1) above is "Yes", does your state also have access to Border States' PDMP information?

☐Yes ☐No

c) If the answer to (number 1) above is "Yes", does your state also have PDMP data integrated into your point-of-sale (POS) edits?

☐Yes ☐No

2. Does your state or your professional board require prescribers to access the PDMP patient history before prescribing controlled substances?

☒Yes ☐No, please explain: _____

a) If the answer to (number 2) above is "Yes", are there protocols involved in checking the PDMP?

☒Yes, please explain:

Prescribers are required to check the PDMP under the following circumstances:

- The first time a patient is prescribed, ordered, administered, or furnished a controlled substance, unless an exemption applies.
- Within the twenty-four hour period, or the previous business day, before prescribing, ordering, administering, or furnishing a controlled substance, unless an exemption applies.
- Before subsequently prescribing a controlled substance, if previously exempt.
- At least once every six months if the controlled substance remains a part of the patient's treatment plan.

Exemptions include:

- While the patient is admitted to, or during an emergency transfer between a:
  - Licensed Clinic, or
  - Outpatient Setting, or
  - Health Facility, or
  - County Medical Facility
- In the emergency department of a general acute care hospital, and the controlled substance does not exceed a non-refillable seven-day supply.
- As part of a patient's treatment for a surgical procedure, and the controlled substance does not exceed a non-refillable seven-day supply when a surgical procedure is performed at a:
  - Licensed Clinic, or
  - Outpatient Setting, or
  - Health Facility, or
  - County Medical Facility, or
  - Place of Practice (defined as a Dental Office pursuant to Business and Professions Code § 1658)
- The patient is receiving hospice care.

☐No

b) Are providers required to have protocols for responses to information from the PDMP that is contradictory to the direction that the practitioner expects from the client?

☐Yes ☒No

c) If a provider is not able to conduct PDMP check, does your state require the prescriber to document a good faith effort, including the reasons why the provider was not able to conduct the check?

☒Yes
☐No, please explain: _____

If the answer to (2c) above is "Yes," does your state require the provider to submit, upon request, documentation to the State?

☐Yes

☒No, please explain: The prescriber must document the reason for not consulting the PDMP in the patient's medical record.

3. Does the State require pharmacists to check the PDMP prior to dispensing?

☐Yes
☒No, please explain: The mandatory PDMP consultation requirement does not apply to dispensing pharmacists.

a) If the answer to (number 3) above is "Yes", are there protocols involved in checking the PDMP?

☐Yes, please explain: _____

☐No

4. In the State's PDMP system, which of the following pieces of information with respect to a beneficiary is available to prescribers as close to real-time as possible? Check **all** that apply.

☒PDMP drug history
☐The number and type of controlled substances prescribed to and dispensed to the beneficiary during at least the most recent 12-month period
☐The name, location, and contact information, or other identifying number, such as a national provider identifier, for previous beneficiary fills
☐Multiple emergency room (ER) visits
☐Prescription Drug Monitoring Program (PDMP) data
☐Other, please explain: _____

a) Are there barriers that hinder the Medicaid agency from fully accessing the PDMP that prevent the program from being utilized the way it was intended to be to curb FWA?

☒Yes, please explain the barriers (i.e., lag time in prescription data being submitted, prescribers not accessing, pharmacists unable to view prescription history before filling script):

- Inability to access border states' PDMP information
- Lag time for prescription data being submitted
- Ambiguous regulations governing access to PDMP data

☐No

5. Please specify below the following information for the 12-month reporting period for this survey. Note: Mandatory reporting will be required in FFY2023 under section 1927(g)(3)(D) of the Act.

   a) The percentage of covered providers who checked the prescription drug history of a beneficiary through a PDMP before prescribing a controlled substance to such an individual:

      Unknown %

   b) Average daily morphine milligram equivalent (MME) prescribed for controlled substances per covered individuals:

      Unknown MMEs

   c) Average daily MME prescribed for controlled substances per covered individual who are receiving opioids:

      Unknown MMEs

   d) Please complete Tables 3, 4, 5 and 6 below. Specify the controlled substances prescribed based on claim count (by generic ingredient(s)) and within each population during this FFY reporting period.

Table 3: Opioid Controlled Substances by Population

Column 1 Population	Column 2 Total Number of Beneficiaries within Each Age Group	Column 3 Total Number of Unique Beneficiaries within Each Age Group Receiving an Opioid Controlled Substance in the 12 Month Reporting Period	Column 4 Percentage within Each Age Group Receiving an Opioid Controlled Substance in the 12 Month Reporting Period	Column 5 Top 3 Opioid Controlled Substances Received within Each Age Group (Generic Ingredient) in the 12 Month Reporting Period	Column 6 Number of Unique Beneficiaries within Each Age Group Receiving the Opioid Controlled Substance (Specified in Column 5) in the 12 Month Reporting Period	Column 7 Percentage of Age Group Receiving the Opioid Controlled Substance (Specified in Column 5) in the 12 Month Reporting Period
0-18 yrs.						
19-29 yrs.						
30-39 yrs.						
40-49 yrs.						
50-59 yrs.						
60-69 yrs.						
70-79 yrs.						
80+ yrs.						
Individuals with Disabilities Utilizing State Eligibility Categories						

Table 4: Top Sedative/Benzodiazepine Controlled Substances by Population
When listing the controlled substances in different drug categories, for the purposes of Table 4 below, please consider long and short acting benzodiazepines to be in the same category.

Column 1 Population	Column 2 Total Number of Beneficiaries within Each Age Group	Column 3 Total Number of Unique Beneficiaries within Each Age Group Receiving a Sedative/ Benzodiazepine in the 12 Month Reporting Period	Column 4 Percentage within Each Age Group Receiving a Sedative/ Benzodiazepine in the 12 Month Reporting Period	Column 5 Top 3 Sedative/ Benzodiazepine Received within Each Age Group (Generic Ingredient) in the 12 Month Reporting Period	Column 6 Number of Unique Beneficiaries within Each Age Group Receiving the Sedative/ Benzodiazepine (Specified in Column 5) in the 12 Month Reporting Period	Column 7 Percentage of Age Group Receiving the Sedative/ Benzodiazepine (Specified in Column 5) in the 12 Month Reporting Period
0-18 yrs.						
19-29 yrs.						
30-39 yrs.						
40-49 yrs.						
50-59 yrs.						
60-69 yrs.						
70-79 yrs.						
80+ yrs.						
Individuals with Disabilities Utilizing State Eligibility Categories						

Table 5: Top Stimulant/ADHD Controlled Substances by Population

When listing the controlled substances in different drug categories, for the purposes of Table 5 below, please consider long and short acting ADHD medications to be in the same category.

Column 1 Population	Column 2 Total Number of Beneficiaries within Each Age Group	Column 3 Total Number of Unique Beneficiaries within Each Age Group Receiving a Stimulant/ADHD medication in the 12 Month Reporting Period	Column 4 Percentage within Each Age Group Receiving a Stimulant/ADHD medication in the 12 Month Reporting Period	Column 5 Top 3 Stimulant/ ADHD medications Received within Each Age Group (Generic Ingredient) in the 12 Month Reporting Period	Column 6 Number of Unique Beneficiaries within Each Age Group Receiving the Stimulant/ ADHD medication (Specified in Column 5) in the 12 Month Reporting Period	Column 7 Percentage of Age Group Receiving the Stimulant/ ADHD medication (Specified in Column 5) in the 12 Month Reporting Period
0-18 yrs.						
19-29 yrs.						
30-39 yrs.						
40-49 yrs.						
50-59 yrs.						
60-69 yrs.						
70-79 yrs.						
80+ yrs.						
Individuals with Disabilities Utilizing State Eligibility Categories						

Table 6: Populations on 2 or more Controlled Substances in Different Drug Categories

When listing the controlled substances in different drug categories, for the purposes of Table 6 below, please consider long and short acting opioids to be in the same category. Please follow this approach for long and short acting ADHD medications and benzodiazepines in this table as well.

Column 1 Population	Column 2 Total Number of Beneficiaries within Each Age Group	Column 3 Total Number of Unique Beneficiaries within Each Age Group Receiving 2 or more Controlled Substances in Different Drug Categories per Month Averaged for the 12 Month Reporting Period	Column 4 Percentage of Age Group Receiving 2 or more Controlled Substances in Different Drug Categories per Month Averaged for the 12 Month Reporting Period	Column 6 Number of Unique Beneficiaries within Each Age Group Receiving 3 or more Controlled Substances in Different Drug Categories per Month Averaged for the 12 Month Reporting Period	Column 7 Percentage of Age Group Receiving 3 or more Controlled Substances in Different Drug Categories per Month Averaged for the 12 Month Reporting Period
0-18 yrs.					
19-29 yrs.					
30-39 yrs.					
40-49 yrs.					
50-59 yrs.					
60-69 yrs.					
70-79 yrs.					
80+ yrs.					
Individuals with Disabilities Utilizing State Eligibility Categories					

i. If there is additional information you want to provide for the previous 12-month reporting period, please explain below:

ii. If any of the information requested is not being reported above, please explain below:
Currently, there is no protocol that allows the state Medicaid program to access the PDMP for reporting purposes.

6. Have you had any changes to your state's PDMP during this reporting period that have improved the Medicaid program's ability to access PDMP data?

☐Yes ☒No

If "Yes" please explain:

_____

7. In this reporting period, have there been any data or privacy breaches of the PDMP or PDMP data?

☐Yes ☒No

If "Yes" please summarize the breach, number of individuals impacted, a description of the steps the State has taken to address each such breach, and if law enforcement or the affected individuals were notified of the breach:

_____

C. OPIOIDS

1. Do you currently have POS edits in place to limit the quantity dispensed of an initial opioid prescription?

☒Yes, for **all** opioids ☐Yes, for some opioids ☐No for **all** opioids

Please explain response above: Claims for all controlled drug products, including opioids (DEA schedule 2-5) have a maximum days' supply of 35 days. Prior authorization is required for claims submitted greater than 35 days. This limit does not apply to initial opioid prescriptions for opioid naïve patients or buprenorphine products.

a) What is the maximum number of days allowed for an initial opioid prescription for an opioid naïve patient?

_7_ # of days

b) Does your state have POS edits in place to limit days' supply of subsequent opioid prescriptions? If yes, please indicate your days supply limit.

☐ 24-day supply
☐ 30-day supply
☐ 34-day supply
☐ 90-day supply
☒ Other, please explain: 35-day supply
☐ No

2. Does your state have POS edits in place to limit the quantity dispensed of short-acting (SA) opioids?

☒Yes, please specify limit. # __120__ units.

☐No, please explain: _____

☐Other, please explain: _____

3. Does your state currently have POS edits in place to limit the quantity dispensed of long-acting opioids?

☒Yes, please specify limit. # 90 units.

☐No, please explain: _____

☐Other, please explain: _____

4. Do you have measures other than restricted quantities and days' supply in place to either monitor or manage the prescribing of opioids?

☒Yes ☐No

If "Yes," please check all that apply:

☐ Pharmacist override
☒ Deny claim and require PA
☒ Intervention letters
☒ MME daily dose program
☐ Step therapy or clinical criteria
☐ Requirement that patient has a pain management contract or Patient-Provider agreement
☐ Requirement that prescriber has an opioid treatment plan for patients
☐ Require documentation of urine drug screening results
☐ Require diagnosis
☒ Require PDMP checks
☒ Workgroup to address opioids
☐ Other, please specify: _____

Please provide details on these opioid prescribing controls in place:
Deny claim and require PA – Restrictions that may deny claim and require PA include, but are not limited to, age restrictions and duration of therapy restrictions.

Intervention letters – In FFY 2021, intervention letters were sent to prescribers for the following topics:

- Dentists and oral surgeons with the highest percentage of paid claims for opioids with a days' supply greater than three days
- Tapering guidelines for patients with concomitant use of opioids and benzodiazepines.

Morphine Milligram Equivalent (MME) daily dose program - For the treatment of chronic pain, dose is to not exceed 500 MME/daily without an approved *Treatment Authorization Request*. This safety edit assists in identifying members at potentially high-clinical risk who may benefit from close monitoring and care coordination.

Require PDMP checks - Assembly Bill 2760 (Wood, Chapter 324) was signed into law

in 2018 and became effective on January 1, 2019. California prescribers are now required to offer a prescription to a patient for either naloxone or another drug approved by the U.S. Food and Drug Administration (FDA) for the complete or partial reversal of opioid-induced respiratory depression, as a rescue medication when one or more of the following conditions are present:

- The prescription dosage for the patient is ≥ 90 mg MME/day.
- An opioid medication is prescribed concurrently with a prescription for a benzodiazepine.
- The patient presents with an increased risk for overdose, including a history of overdose, a history of substance use disorder, or a risk for returning to a high dose of opioid medication to which the patient is no longer tolerant.

The bill also requires a prescriber, consistent with the existing standard of care, to provide education on overdose prevention and the use of naloxone or other similar drug approved by the FDA to a patient and his or her designee or, if the patient is a minor, to the patient's parent or guardian.

Workgroups to address opioids – California has a Prescription Drug Overdose Prevention Initiative. The goals of the initiative include increasing the number of active buprenorphine prescribers, increasing the number of naloxone claims, decreasing all-cause overdose mortality, reducing the concomitant use of benzodiazepines and opioids, and reducing opioid claims > 90 mg MEDD.

If "No," please explain what you do in lieu of the above or why you do not have measures in place to either manage or monitor the prescribing of opioids.

_____

5. Do you have POS edits to monitor duplicate therapy of opioid prescriptions? This excludes regimens that include a single extended-release product and a breakthrough short acting agent.

   ☒Yes ☐No

   Please explain: POS edits are in place to monitor duplicate therapy of opioid prescriptions that do not have an approved *Treatment Authorization Request*.

6. Does your state have POS edits to monitor early refills of opioid prescriptions dispensed?

   ☒Yes ☐No

   Please explain your response: POS edits are in place to monitor early refills of opioid prescriptions that do not have an approved *Treatment Authorization Request*.

7. Does your state have a comprehensive automated retrospective claims review process to monitor opioid prescriptions exceeding these state limitations (early refills,

duplicate fills, quantity limits and days' supply)?

☐Yes, please explain in detail the scope and nature of these retrospective reviews
☒No, please explain: While there is a regular, comprehensive claims review to monitor opioid prescriptions exceeding these state limitations, the review process is not automated.

8. Does your state currently have POS edits in place or automated retrospective claims review to monitor opioids and benzodiazepines being used concurrently?

☐Yes, POS edits only
☐Yes, Automated retrospective reviews only
☒Yes, both POS edits and automated retrospective reviews

Please explain in detail scope and nature of reviews and edits: Effective June 1, 2018, the Medi-Cal fee-for-service prospective DUR system was updated to generate an alert for additive toxicity (AT) when a patient reaches a threshold of four active prescriptions within the following therapeutic categories: opioid pain or cough medications, benzodiazepines, skeletal muscle relaxants, other sleep drugs and tranquilizers (non-benzodiazepine), antipsychotic medications, and other selected psychotropic medications with central nervous system (CNS) depressant properties. One mailing on this topic was initiated in FFY2019 after retrospective reviews showed beneficiaries with concurrent use of opioids, benzodiazepines, and two additional medications with CNS depressant properties. In addition, the total number of Medi-Cal FFS beneficiaries with concomitant use of opioids and benzodiazepines during each calendar month has been tracked each calendar month since October 1, 2019.

☐No, please explain: _____

9. Does your state currently have POS edits in place or automated retrospective claims review to monitor opioids and sedatives being used concurrently?

☒Yes, POS edits only
☐Yes, Automated retrospective claim reviews
☐Yes, both POS edits and automated retrospective claim reviews

Please explain in detail scope and nature of reviews and edits: Effective June 1, 2018, the Medi-Cal fee-for-service prospective DUR system was updated to generate an alert for additive toxicity (AT) when a patient reaches a threshold of four active prescriptions within the following therapeutic categories: opioid pain or cough medications, benzodiazepines, skeletal muscle relaxants, other sleep drugs and tranquilizers (non-benzodiazepine), antipsychotic medications, and other selected psychotropic medications with central nervous system (CNS) depressant properties.

☐No, please explain: _____

10. Does your state currently have POS edits in place or a retrospective claims review to monitor opioids and antipsychotics being used concurrently?

☐ Yes, POS edits only
☐ Yes, Automated retrospective claim reviews
☒ Yes, both POS edits and automated retrospective claim reviews

Please explain in detail scope and nature of reviews and edits: Effective June 1, 2018, the Medi-Cal fee-for-service prospective DUR system was updated to generate an alert for additive toxicity (AT) when a patient reaches a threshold of four active prescriptions within the following therapeutic categories: opioid pain or cough medications, benzodiazepines, skeletal muscle relaxants, other sleep drugs and tranquilizers (non-benzodiazepine), antipsychotic medications, and other selected psychotropic medications with central nervous system (CNS) depressant properties. In addition, the total number of Medi-Cal FFS beneficiaries with concomitant use of opioids and antipsychotics during each calendar month has been tracked retrospectively each calendar month since October 1, 2019.

☐ No, please explain: _____

11. Does your state have POS safety edits or perform any automated retrospective claim review and/or provider education in regard to beneficiaries with a diagnosis history of opioid use disorder (OUD) or opioid poisoning diagnosis? L SEP

☐ Yes, POS edits only
☒ Yes, automated retrospective claims review and/or provider education
☐ Yes, both POS edits and automated retrospective claims review and/or provider education
☐ No

If "Yes," automated retrospective claims reviews and/or provider education, please indicate how often.

☒ Monthly
☐ Quarterly
☐ Semi-Annually
☐ Annually
☒ Ad hoc
☐ Other, please explain.

_____

Please explain nature and scope of edits, reviews and/or provider education reviews performed: Retrospective reviews of beneficiaries with a diagnosis history of opioid use disorder (OUD) or opioid poisoning diagnosis are performed at least monthly and on an ad-hoc basis.

If "No," does your state plan on implementing automated retrospective claims review and/or provider education in regard to beneficiaries with a diagnosis history of OUD or opioid poisoning in the future?

☐ Yes, when does your state plan on implementing? _____
☐ No, please explain: _____

12. Does your state Medicaid program develop and provide prescribers with pain management or opioid prescribing guidelines?

☒Yes ☐No

If "Yes," please check **all** that apply:
☒ Your state Medicaid agency refers prescribers to the CDC's Guideline for Prescribing Opioids for Chronic Pain
☒ Other guidelines, please identify: The Medical Board of California Guidelines for Prescribing Controlled Substances for Pain.

If "No," please explain why no guidelines are offered: _____

13. Does your state have a drug utilization management strategy that supports abuse deterrent opioid use to prevent opioid misuse and abuse (i.e., presence of an abuse deterrent opioid with preferred status on your preferred drug list)?

☒Yes ☐No

If "Yes," please explain: Effective August 1, 2017, multiple strengths of morphine sulfate/naltrexone were added to the Medi-Cal List of Contract Drugs.

14. Were there COVID-19 ramifications on edits and reviews on controlled substances during the public health emergency?

☐ Yes, please explain: _____
☒ No

D. MORPHINE MILLIGRAM EQUIVALENT (MME) DAILY DOSE

1. Have you set recommended maximum MME daily dose measures?

☒Yes ☐No

a) If "Yes," what is your maximum morphine equivalent daily dose limit in milligrams?

☐ Less than 50 MME, please specify: _____mg per day

☐ 50 MME
☐ 70 MME
☐ 80 MME
☐ 90 MME
☐ 100 MME
☐ 120 MME
☐ 200 MME
☒ Greater than 200 MME, please specify: 500 mg per day

b) If "Yes," please explain nature and scope of dose limit (i.e., who does the edit apply to? Does the limit apply to **all** opioids? Are you in the process of tapering patients to achieve this limit?): For the treatment of chronic pain, dose is to not exceed 500 MME/daily without an approved *Treatment Authorization Request*. This safety edit assists in identifying members at potentially-high clinical risk who may benefit from close monitoring and care coordination.

If "No," please explain the measure or program you utilize: _____

2. Does your state have an edit in your POS system that alerts the pharmacy provider that the MME daily dose prescribed has been exceeded?

☐Yes ☒No

If "Yes," do you require PA if the MME limit is exceeded?

☐Yes ☐No

3. Does your state have automated retrospective claim reviews to monitor the MME total daily dose of opioid prescriptions dispensed?

☐ Yes
☒ No, please explain: We have completed several retrospective claim reviews to monitor total MME daily dose of opioid prescriptions dispensed, but they are not automated.

4. Do you provide information to your prescribers on how to calculate the morphine equivalent daily dosage or do you provide a calculator developed elsewhere? [SEP]

☒Yes ☐No

a) Please name the developer of the calculator:

☒ CDC
☐ Academic Institution
☐ Other, please specify:

b) How is the information disseminated? Check all that apply.

☒ Website
☒ Provider notice
☐ Educational seminar
☒ Other, please explain.

In February 2019, the Medi-Cal DUR program published an educational bulletin entitled, "*Clinical Review Update: Morphine Equivalent Daily Dose"* to the Medi-Cal DUR website. This bulletin defined morphine equivalent daily dose (MEDD) and provided evidence to support using MEDD as an indicator of potential dose-related risk for prescription opioid overdose. The bulletin provided links to several online MEDD calculators, as well as additional resources to providers. The bulletin was also emailed to all providers who subscribe to the Medi-Cal Subscription Service and remained on the Medi-Cal DUR website throughout FFY 2021.

E. OPIOID USE DISORDER (OUD) TREATMENT

1. Does your state have utilization controls (i.e., preferred drug list (PDL), PA, quantity limit (QL)) to either monitor or manage the prescribing of Medication Assisted Treatment (MAT) for OUD?

☐Yes, please explain:

☒No

2. Does your Medicaid program set total mg per day limits on the use of buprenorphine and buprenorphine/naloxone combination drugs?

☐Yes ☒No

If "Yes", please specify the total mg/day?

☐ 12 mg
☐ 16 mg
☐ 24 mg
☐ 32 mg
☐ Other, please explain:

3. What are your limitations on the allowable length of this treatment?

☒ No limit
☐ 3 months or less
☐ 6 months
☐ 12 months
☐ 24 months
☐ Other, please explain.

4. Does your state require that the maximum mg per day allowable be reduced after a set period of time?

☐Yes ☒No

a) If "Yes," what is your reduced (maintenance) dosage?
☐ 8 mg
☐ 12 mg
☐ 16 mg
☐ Other, please explain.

_____

b) If "Yes," what are your limitations on the allowable length of the reduced dosage treatment?

☐ No limit
☐ 6 months
☐ 12 months
☐ Other, please explain.

_____

5. Does your state have at least one preferred buprenorphine/naloxone combination product available without PA?

☒Yes ☐No

6. Does your state currently have edits in place to monitor opioids being used concurrently with any buprenorphine drug or any other form of MAT?

☐ Yes
☒ No
☐ Other, please explain.

_____

If "Yes," can the POS pharmacist override the edit?

☐Yes ☐No

7. Is there at least one formulation of naltrexone for OUD available without PA?

☒Yes ☐No

8. Does your state have at least one naloxone opioid overdose product available without PA?

☒Yes ☐No

9. Does your state retrospectively monitor and manage appropriate use of naloxone to persons at risk of overdose?

☒Yes
☐No, please explain: _____

10. Does your State Board of Professional Regulations/Board of Pharmacy/Board of Medicine and/or state Medicaid program allow pharmacists to dispense naloxone prescribed independently or by collaborative practice agreements, standing orders, or other predetermined protocols?

☒ Yes, State Board of Professional Regulations/Board of Pharmacy/Board of Medicine and/or state Medicaid agency under protocol
☐ Yes, prescribed independently
☐ No

F. OUTPATIENT TREATMENT PROGRAMS (OTP)

1. Does your state cover OTPs that provide Behavioral Health (BH) and MAT services?

☒Yes ☐No, please explain: _____

If "Yes", is a referral needed for OUD treatment through OTPs?

☐Yes ☒No
Please explain: The state covers OUD treatment through OTPs and does not require a referral or prior authorization.

2. Does your state cover Medicaid program cover buprenorphine or buprenorphine/naloxone for diagnosis of OUD as part of a comprehensive MAT treatment plan through OTPs?

☒Yes ☐No, please explain: _____

3. Does your state Medicaid program cover naltrexone for diagnosis of OUD as part of a comprehensive MAT treatment plan through OTPs?

☒Yes ☐No, please explain: _____

4. Does your state Medicaid program cover Methadone for a substance use disorder (i.e., OTPs, Methadone Clinics)?

☒Yes ☐No

G. PSYCHOTROPIC MEDICATION

ANTIPSYCHOTICS

1. Does your state currently have restrictions in place to limit the quantity of antipsychotics?

☐Yes ☒No

Please explain restrictions or N/A: An approved *Treatment Authorization Request* is required for any antipsychotic medication for all Medi-Cal beneficiaries 0 – 17 years of age. An approved *Treatment Authorization Request* is also required for beneficiaries residing in skilled nursing facilities (SNFs).

2. Does your state you have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children?

☒Yes ☐No

a) If "Yes," does your state either manage or monitor:

☐ Only children in foster care
☒ All children
☐ Other, please explain.
_____

b) If "Yes," does your state have edits in place to monitor (check all that apply):
☒ Child's Age, please specify age limit: 0 – 17 years of age, depending on drug
☒ Dosage
☒ Indication
☒ Polypharmacy
☐ Other, please explain:

c) Please briefly explain the specifics of your documented antipsychotic monitoring program(s).

An approved *Treatment Authorization Request* is required for any antipsychotic medication for all Medi-Cal beneficiaries 0 – 17 years of age.

In addition, DHCS Pharmacy Benefits Division, DHCS Behavioral Health Division, and California Department of Social Services (CDSS) continue to collaborate on a Quality Improvement Project entitled, "Improving the Use of Psychotropic Medication among Children and Youth in Foster Care." The purpose of this program is to reduce the rate of antipsychotic polypharmacy, improve the rate of compliance with age-specific antipsychotic dose recommended guidelines, and improve the rate of children and youth in foster care with at least one psychotropic medication who have an annual metabolic risk assessment. The goals are to reduce polypharmacy and improve compliance with dosing guidelines and annual metabolic risk assessment.

If "No," does your state plan on implementing a program in the future?

☐ Yes, please specify when do you plan on implementing a program to monitor the appropriate use of antipsychotic drugs in children: _____

☐ No, please explain why you will not be implementing a program to monitor the appropriate use of antipsychotic drugs in children: _____

STIMULANTS

3. Does your state currently have restrictions in place to limit the quantity of stimulants?

☐ Yes ☒ No

4. Does your state have any documented program in place to either manage or monitor the appropriate use of stimulant drugs in children?

☒ Yes ☐ No

a) If "Yes," does your state either manage or monitor:

☐ Only children in foster care
☒ All children
☐ Other, please explain.

_____

b) If "Yes," do you have edits in place to monitor (check all that apply):
☒ Child's Age, please specify age limit: 0 – 17 years of age, depending on drug
☒ Dosage
☒ Indication
☒ Polypharmacy
☐ Other, please explain:

c) Please briefly explain the specifics of your documented stimulant monitoring program(s). The stimulant monitoring program includes both ProDUR and RetroDUR

components. During FFY 2021 there were documented restrictions to use for all stimulants. These restrictions varied by drug, and may have included age limits, indication restrictions (for attention deficit disorder), and/or ProDUR edits for both high and low dosage. In addition, retrospective utilization of all psychotherapeutic medications in children younger than 18 years of age is reviewed on at least an annual basis.

If "No," does your state plan on implementing a program in the future?

☐Yes, please specify when do you plan on implementing a program to monitor the appropriate use of stimulant drugs in children.

_____

☐No, please explain why you will not be implementing a program to monitor the appropriate use of stimulant drugs in children.

_____

ANTIDEPRESSANTS

5. Does your state have any documented program in place to either manage or monitor the appropriate use of antidepressants in children?

☒Yes ☐No

a) If "Yes," does your state either manage or monitor:

☐ Only children in foster care
☒ All children
☐ Other, please explain.

_____

b) If "Yes," do you have edits in place to monitor (check all that apply):
☒ Child's Age, please specify age limit: 0 – 17 years of age, depending on drug
☒ Dosage
☐ Indication
☒ Polypharmacy
☐ Other, please explain:

c) Please briefly explain the specifics of your documented antidepressant monitoring program(s). The antidepressant monitoring program includes both ProDUR and RetroDUR components. During FFY 2021 there were documented restrictions to use for most antidepressant medications. These restrictions varied by drug, and may have included age limits and/or ProDUR edits for therapeutic and ingredient duplication and both high and low dosage. In addition, retrospective utilization of all psychotherapeutic medications in children younger than 18 years of age is reviewed on at least an annual basis.

If "No," does your state plan on implementing a program in the future?

☐Yes, please specify when do you plan on implementing a program to monitor the appropriate use of antidepressant drugs in children.

_____

☐No, please explain why you will not be implementing a program to monitor the appropriate use of antidepressant drugs in children.

_____

MOOD STABILIZERS

6. Does your state have any documented program in place to either manage or monitor the appropriate use of mood stabilizing drugs in children?

☒Yes ☐No

a) If "Yes," does your state either manage or monitor:

☐ Only children in foster care
☒ All children
☐ Other, please explain.

_____

b) If "Yes," do you have edits in place to monitor (check all that apply):
☒ Child's Age, please specify age limit: 12 years of age
☒ Dosage
☐ Indication
☒ Polypharmacy
☐ Other, please explain:

c) Please briefly explain the specifics of your documented mood stabilizer monitoring program(s). The mood stabilizer monitoring program includes both ProDUR and RetroDUR components. During FFY 2021 there were documented restrictions to use for mood stabilizer medications. These restrictions include age limits and/or ProDUR edits for both high and low dosage. In addition, retrospective utilization of all psychotherapeutic medications in children younger than 18 years of age is reviewed on at least an annual basis.

If "No," does your state plan on implementing a program in the future?

☐Yes, please specify when do you plan on implementing a program to monitor the appropriate use of mood stabilizing drugs in children.

_____

☐No, please explain why you will not be implementing a program to monitor the appropriate use of mood stabilizing drugs in children.

_____

ANTIANXIETY/SEDATIVES

7. Does your state have any documented program in place to either manage or monitor the appropriate use of antianxiety/sedative drugs in children?

☒Yes ☐No

a) If "Yes," does your state either manage or monitor:

☐ Only children in foster care
☒ All children
☐ Other, please explain.

_____

b) If "Yes," do you have edits in place to monitor (check all that apply):
☒ Child's Age, please specify age limit: 18 years of age
☒ Dosage
☒ Indication
☒ Polypharmacy
☐ Other, please explain:

c) Please briefly explain the specifics of your documented mood stabilizer monitoring program(s). The mood stabilizer monitoring program includes both ProDUR and RetroDUR components. During FFY 2021 there were documented restrictions to use for most antianxiety/sedative medications. These restrictions include age limits, indication restrictions (for acute epilepsy, for example), and and/or ProDUR edits for therapeutic and ingredient duplication and both high and low dosage. In addition, retrospective utilization of all psychotherapeutic medications in children younger than 18 years of age is reviewed on at least an annual basis.

If "No," does your state plan on implementing a program in the future?

☐Yes, please specify when do you plan on implementing a program to monitor the appropriate use of antianxiety/sedative drugs in children.

_____

☐No, please explain why you will not be implementing a program to monitor the appropriate use of antianxiety/sedative drugs in children.

_____

IX. INNOVATIVE PRACTICES

1. Does your state participate in any demonstrations or have any waivers to allow importation of certain drugs from Canada or other countries that are versions of FDA-approved drugs for dispensing to Medicaid beneficiaries?

   ☐Yes, please explain: _____

   ☒No

2. **Summary 5 – Innovative Practices**

   Summary 5 - Innovative Practices should discuss development of innovative practices during the past year (i.e. Substance Use Disorder, Hepatitis C, Cystic Fibrosis, MME, and Value Based Purchasing). Please describe in detailed narrative below any innovative practices that you believe have improved the administration of your DUR program, the appropriateness of prescription drug use and/or have helped to control costs (i.e., disease management, academic detailing, automated PA, continuing education programs).

   Much of FFY 2021 was dedicated to the transition of pharmacy services from the 26 managed care plans to Medi-Cal Fee-for-Service, which began on January 1, 2022. The Medi-Cal pharmacy benefits and services administered by DHCS in the FFS delivery system will be identified collectively as "Medi-Cal Rx." The goals of this transition are as follows:

   - Standardize the Medi-Cal pharmacy benefit statewide, under one delivery system.
   - Improve access to pharmacy services with a network that includes approximately 94% of the state's pharmacies.
   - Apply statewide utilization management protocols to all outpatient drugs.
   - Strengthen California's ability to negotiate state supplemental drug rebates with pharmaceutical manufacturers.

   Medi-Cal Rx encompasses all pharmacy services billed as a pharmacy claim, including but not limited to outpatient drugs (prescription and over-the counter), including physician-administered drugs (PADs), enteral nutrition products, and medical supplies. Medi-Cal Rx will not include pharmacy services billed as a medical (professional) or institutional claim.

   In addition, during FFY 2021 the Board continued to collaborate with key state agencies and national experts, and actively worked to incorporate a variety of Medi-Cal MCP best practices across multiple plans into the Board meeting agenda.

   Presentations for FFY 2021 included:

   - COVID-19 Epidemiology
   - Managed Care Plan Quality Improvement Projects
   - COVID-19 Vaccines

- Medication Therapy Management
- Hormonal Contraception
- Medication Reconciliation

Finally, Medication Therapy Management (MTM) was added as a new benefit during FFY 2021. The State Plan Amendment was submitted and subsequently approved by CMS on September 15, 2021.

X. MANAGED CARE ORGANIZATIONS (MCOs)

1. How many MCOs are enrolled in your state Medicaid program?

   __26__ MCO(s) (Insert number of MCOs in the space including 0 if none)

   If "Zero" or "None," please skip the rest of this section.

2. Is your pharmacy program included in the capitation rate (carved in)?

   ☐Yes ☐No ☒Partial

   If "partial," please specify the drug categories that are carved out.
   - Selected HIV/AIDS/Hepatitis B treatment drugs;
   - Selected alcohol and heroin detoxification and dependency treatment drugs;
   - Selected coagulation factors; and
   - Selected drugs used to treat psychiatric conditions (including antipsychotics and MAO inhibitors)

3. Contract updates between state and MCOs addressing DUR provisions in Section 1004 of the SUPPORT for Patients and Communities Act are required based on 1902(oo). If covered outpatient drugs are included in an MCO's covered benefit package, has the State updated their MCOs' contracts for compliance with Section 1004 of the SUPPORT for Patients and Communities Act?

   ☒Yes, contracts are updated to address each provision. Please specify effective date: 10/1/2019

   ☐No, contracts are not updated, please explain: _____

   a) Is the state complying with Federal law and monitoring MCO compliance on the SUPPORT for Patients and Communities Act provisions?

      ☒Yes, state is complying with Federal law and monitoring MCO compliance on SUPPORT for Patients and Communities Act provisions. Please explain monitoring activities.

Per All Plan Letter 19-012, all MCO policies and procedures addressing the requirements of the SUPPORT Act have been submitted by each MCO and reviewed for compliance.

☐No, please explain: _____

4. Does the state set requirements for the MCO's pharmacy benefit (i.e., same PDL, same ProDUR/RetroDUR)?

☒Yes ☐No

a) If "Yes," do please check **all** requirements that apply below:

☒ Formulary Reviews
☐ Same PDL
☐ Same ProDUR
☐ Same RetroDUR
☐ No state PDL

b) If "Yes," please briefly explain your policy:

Medi-Cal MCOs are required to provide a pharmacy benefit that is comparable to the Medi-Cal FFS pharmacy program and their preferred drug lists (PDLs) are required to be comparable to the Medi-Cal List of Contract Drugs. While all drugs included on the Medi-Cal List of Contract Drugs do not need to be included on the MCOs' PDLs, comparable means that the drugs on the PDLs must have the same mechanism of action sub-class within all major therapeutic categories of drugs included in the Medi-Cal List of Contract Drugs.

Starting in FFY 2018, the DUR Board expanded to become the Global Medi-Cal DUR Board, with MCO representatives now included as Board members. MCOs utilize the Global Medi-Cal DUR Board and educational components of the Medi-Cal DUR program. However, MCOs maintain their current proprietary claims processing procedures and protocols and MCOs individually administer the systematic components related to the prospective and retrospective DUR processes. As is the case with the Fee-For-Service (FFS) program, MCOs are not required to implement all DUR Board recommended actions, nor are they required to mirror the Medi-Cal DUR activities.

If "No," do you plan to set standards in the future?

☐Yes
☐No, please explain: _____

5. Is the RetroDUR program operated by the state or by the MCOs or does your state use a combination of state interventions as well as individual MCO interventions?

☐ State operated
☐ MCO operated
☒ State uses a combination of state interventions as well as individual MCO interventions

6. Indicate how the State oversees the FFS and MCO RetroDUR programs? Please explain oversight process.

   The oversight process includes evaluating MCO annual report surveys, reviewing MCO policies and procedures, and requiring MCO participation in Global Medi-Cal DUR Board meetings and dissemination of FFS RetroDUR educational bulletins and alerts.

7. How does the state ensure MCO compliance with DUR requirements described in Section 1927(g) of the Act and 42 CFR part 456, subpart K?

   MCO compliance with DUR requirements is ensured through a detailed review of each MCO's annual report survey.

8. Did **all** of your managed care plans submit their DUR reports?

   ☒ Yes
   ☐ No, please explain: _____

XI. EXECUTIVE SUMMARY

1. **Summary 6 - Executive Summary** should provide a brief overview of your program. It should describe 2021 highlights of the program, FFS initiatives, improvements, program oversight of managed care partners when applicable, and statewide (FFS and MCO) initiatives

   The purpose of Drug Utilization Review (DUR) is to improve the quality and cost-effectiveness of drug use by ensuring that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. California's Medi-Cal DUR program is the responsibility of the Department of Health Care Services (DHCS), and includes prospective DUR reviews, retrospective DUR reviews, and educational interventions for providers and pharmacies.

   During federal fiscal year (FFY) 2021, California's Global Medi-Cal DUR Board (the "Board") included eight pharmacists and five physicians, meeting OBRA 1990 requirements. The Board held four meetings in FFY 2021, with each meeting divided up into two distinct sections: 1) old business and follow-ups; and 2) new business that included placeholders for updates from DHCS and the DUR Board, drug utilization reports, prospective and retrospective DUR reviews, and descriptions of educational bulletins and/or alerts.

   The Board is responsible for advising and making recommendations to DHCS for the Medi-Cal population. Over the course of FFY 2021 the Board reviewed prospective DUR criteria for 31 drugs. In addition, retrospective DUR criteria were reviewed for all psychotropic medications used in children and adolescents, opioid medications prescribed by dentists and oral surgeons, opioid medications prescribed in the emergency department and outpatient surgical settings, hepatitis C virus (HCV) medications, and all medications that became available on the Medi-Cal Contract Drugs List in FFY 2019. A total of seven educational bulletins and alerts were published on the Medi-Cal website in order to educate and inform Medi-Cal providers and beneficiaries on timely and relevant topics related to medication use. A total of four educational mailings were sent to selected prescribers to improve the quality of care for Medi-Cal beneficiaries.

   The Board continued to collaborate with key state agencies and national experts in FFY 2021, and actively worked to incorporate a variety of Medi-Cal MCO best practices across multiple plans into the Board meeting agenda. With input provided by the Board, Medication Therapy Management (MTM) was added as a new benefit during FFY 2021.

   This Annual Report was prepared through a collaborative effort between the California Department of Health Care Services, the Global Medi-Cal Drug Use Review Board, and the University of California, San Francisco.

QUARTERLY SUMMARY
GLOBAL MEDI-CAL DRUG USE REVIEW
REPORT PERIOD: 4TH QUARTER 2021 (OCTOBER – DECEMBER 2021)

Executive Summary

The Global DUR quarterly report provides information on retrospective drug utilization for all paid pharmacy claims for beneficiaries in the Medi-Cal program. For this report, the retrospective data cover the fourth quarter of 2021 (2021 Q4).

In 2021 Q4, approximately 31% of eligible Medi-Cal enrollees had a paid pharmacy claim through the Medi-Cal program (**Table 1.1**). This includes 14% of eligible Medi-Cal fee-for-service enrollees and 35% of Medi-Cal managed care plan (MCP) enrollees. Among all Medi-Cal beneficiaries with a paid claim through the Medi-Cal program in 2021 Q4, 8% were FFS enrollees, 92% were MCP enrollees, and less than 1% of beneficiaries had enrollments in both FFS and MCP during the quarter. When data from 2021 Q4 were compared to the prior year (2020 Q4), data from 2021 Q4 showed a 7% increase in total eligible beneficiaries, an 18% increase in total utilizing beneficiaries, and a 9% increase in total paid pharmacy claims.

When beneficiaries eligible for Medi-Cal were stratified by population aid code group (**Tables 1.2 – 1.5**), 32% were Affordable Care Act (ACA), 9% were Optional Targeted Low Income Children (OTLIC), and 15% were Seniors and Persons with Disabilities (SPD). Within the population aid code groups, the vast majority of utilizing beneficiaries were MCP enrollees, including 94% of the ACA population, 99% of the OTLIC population, 92% of the SPD population, and 89% of the remaining (OTHER) population. These tables also include the total number of beneficiaries that were continuously-eligible within each population aid code group. Continuous eligibility is plan-specific and is measured for 2021 Q4 from October 1, 2021 – December 1, 2021.

As shown in **Tables 2.1 – 2.3**, there were double-digit increases in total utilizing beneficiaries and total paid claims for both FFS and MCP enrollees in comparison to the prior-year quarter for the 0 – 12 year age group, most likely due to an Emergency Use Authorizaon (EUA) of a COVID-19 vaccine for children between 5 and 12 years of age in October 2021.

The greatest increase in total utilizing beneficiaries and total paid claims within the top 20 drug therapeutic categories by total utilizing beneficiaries (**Table 3**) was seen in the COVID-19 VACCINES drug therapeutic category, which had just received an EUA at the end of 2020 Q4. Similarly, both COVID-19 VACC, MRNA (PFIZER)/PF and COVID-19 VACC, MRNA (MODERNA)/PF appear within the top 20 drugs by total utilizing beneficiaries with significant increases from the prior year. In addition, 2021 Q4 saw increases in total utilizing beneficiaries and total paid claims from the prior-year quarter (**Table 5**) for the following drugs: ALBUTEROL SULFATE, AMOXICILLIN, and ACETAMINOPHEN.

Tables 4.1 – **4.4** show the top 20 drug therapeutic categories by total continuously-eligible utilizing beneficiaries in 2021 Q4, stratified by population aid code group and **Tables 6.1 – 6.4** show the top 20 drugs by total continuously-eligible utilizing beneficiaries in 2021 Q4, stratified by population aid code group. Within each of these tables, the mean days' supply per utilizing beneficiary is shown for both FFS and MCP enrollees.

Tables 1.1 – 1.5. Summary of Global Medi-Cal Pharmacy Utilization.

Table 1.1 shows pharmacy utilization in the Medi-Cal program, including the percent change from the prior-year quarter. Beneficiaries with enrollments in both FFS and MCP during the quarter may be counted twice (represents 0.4% of utilizing beneficiaries). **Tables 1.2 – 1.5** show pharmacy utilization in the Medi-Cal program, **stratified by population aid code group**.

Table 1.1: Global Medi-Cal Pharmacy Utilization Measures for the Entire Medi-Cal Population			
Category	**Current Quarter 2021 Q4**	**Prior-Year Quarter 2020 Q4**	**% Change from *Prior Year***
Total Eligible Beneficiaries	17,047,619	15,911,066	**7.1%**
Total Utilizing Beneficiaries	5,326,914	4,503,851	**18.3%**
Total Paid Rx Claims	27,492,887	25,006,905	**9.9%**
Average Paid Rx Claims per Eligible Beneficiary	1.61	1.57	**2.6%**
Average Paid Rx Claims per Utilizing Beneficiary	5.16	5.55	**-7.0%**
Fee-for-Service Enrollees			
Total Eligible Beneficiaries	3,140,986	3,008,436	**4.4%**
Total Utilizing Beneficiaries	449,260	412,642	**8.9%**
Total Paid Rx Claims	1,650,413	1,548,554	**6.6%**
Average Paid Rx Claims per Eligible Beneficiary	0.53	0.51	**2.1%**
Average Paid Rx Claims per Utilizing Beneficiary	3.67	3.75	**-2.1%**
Managed Care Plan Enrollees			
Total Eligible Beneficiaries	14,099,284	12,983,109	**8.6%**
Total Utilizing Beneficiaries	4,900,369	4,114,542	**19.1%**
Total Paid Rx Claims	25,840,800	23,469,565	**10.1%**
Average Paid Rx Claims per Eligible Beneficiary	1.83	1.81	**1.4%**
Average Paid Rx Claims per Utilizing Beneficiary	5.27	5.70	**-7.6%**

Table 1.2 shows pharmacy utilization within the **Affordable Care Act (ACA)** population, which consists of the following Adult Expansion aid codes: M1, M2, L1, and 7U. Continuous eligibility is plan-specific and is measured from October 1, 2021 – December 1, 2021.

Among the total utilizing beneficiaries in the ACA population, 44% of FFS enrollees and 61% of MCP enrollees were continuously eligible within the same plan during 2021 Q4.

Table 1.2: Global Medi-Cal Pharmacy Utilization Measures for the ACA Population			
Category	**Current Quarter 2021 Q4**	**Prior-Year Quarter 2020 Q4**	**% Change from *Prior Year***
Total Eligible Beneficiaries	5,394,179	4,843,358	**11.4%**
Total Utilizing Beneficiaries	2,003,928	1,698,821	**18.0%**
Total Paid Rx Claims	11,603,286	10,346,580	**12.1%**
Average Paid Rx Claims per Eligible Beneficiary	2.15	2.14	**0.7%**
Average Paid Rx Claims per Utilizing Beneficiary	5.79	6.09	**-4.9%**
Continuously-Eligible Total Eligible Beneficiaries	*4,511,220*	*4,002,336*	***12.7%***
Continuously-Eligible Total Utilizing Beneficiaries	*1,232,076*	*1,039,309*	***18.5%***
Continuously-Eligible Total Paid Rx Claims	*7,752,519*	*6,947,990*	***11.6%***
Fee-for-Service Enrollees			
Total Eligible Beneficiaries	880,112	885,097	**-0.6%**
Total Utilizing Beneficiaries	132,780	117,952	**12.6%**
Total Paid Rx Claims	541,522	483,489	**12.0%**
Average Paid Rx Claims per Eligible Beneficiary	0.62	0.55	**12.6%**
Average Paid Rx Claims per Utilizing Beneficiary	4.08	4.10	**-0.5%**
Continuously-Eligible Total Eligible Beneficiaries	*583,977*	*536,481*	***8.9%***
Continuously-Eligible Total Utilizing Beneficiaries	*58,482*	*46,548*	***25.6%***
Continuously-Eligible Total Paid Rx Claims	*165,105*	*137,285*	***20.3%***
Managed Care Plan Enrollees			
Total Eligible Beneficiaries	4,627,495	4,093,415	**13.0%**
Total Utilizing Beneficiaries	1,883,889	1,595,142	**18.1%**
Total Paid Rx Claims	11,061,764	9,866,246	**12.1%**
Average Paid Rx Claims per Eligible Beneficiary	2.39	2.41	**-0.8%**
Average Paid Rx Claims per Utilizing Beneficiary	5.87	6.19	**-5.1%**
Continuously-Eligible Total Eligible Beneficiaries	*3,808,138*	*3,328,747*	***14.4%***
Continuously-Eligible Total Utilizing Beneficiaries	*1,144,288*	*960,764*	***19.1%***
Continuously-Eligible Total Paid Rx Claims	*3,676,352*	*3,293,487*	***11.6%***

Table 1.3 shows pharmacy utilization within the **Optional Targeted Low Income Children (OTLIC)** population consists of the following OTLIC aid codes: 2P, 2R, 2S, 2T, 2U, 5C, 5D, E2, E5, E6, E7, H1, H2, H3, H4, H5, M5, T0, T1, T2, T3, T4, T5, T6, T7, T8, and T9. Continuous eligibility is plan-specific and is measured from October 1, 2021 – December 1, 2021.

Among the total utilizing beneficiaries in the OTLIC population, 37% of FFS enrollees and 49% of MCP enrollees were continuously eligible within the same plan during 2021 Q4.

Table 1.3: Global Medi-Cal Pharmacy Utilization Measures for the OTLIC Population			
Category	**Current Quarter 2021 Q4**	**Prior-Year Quarter 2020 Q4**	**% Change from *Prior Year***
Total Eligible Beneficiaries	1,546,888	1,541,332	**0.4%**
Total Utilizing Beneficiaries	339,810	249,282	**36.3%**
Total Paid Rx Claims	871,735	657,214	**32.6%**
Average Paid Rx Claims per Eligible Beneficiary	0.56	0.43	**32.2%**
Average Paid Rx Claims per Utilizing Beneficiary	2.57	2.64	**-2.7%**
Continuously-Eligible Total Eligible Beneficiaries	*1,281,123*	*1,262,265*	***1.5%***
Continuously-Eligible Total Utilizing Beneficiaries	*167,014*	*115,582*	***44.5%***
Continuously-Eligible Total Paid Rx Claims	*587,660*	*429,569*	***36.8%***
Fee-for-Service Enrollees			
Total Eligible Beneficiaries	76,283	93,067	**-18.0%**
Total Utilizing Beneficiaries	5,351	4,352	**23.0%**
Total Paid Rx Claims	12,350	10,325	**19.6%**
Average Paid Rx Claims per Eligible Beneficiary	0.16	0.11	**45.9%**
Average Paid Rx Claims per Utilizing Beneficiary	2.31	2.37	**-2.7%**
Continuously-Eligible Total Eligible Beneficiaries	*36,261*	*37,694*	***-3.8%***
Continuously-Eligible Total Utilizing Beneficiaries	*1,988*	*1,370*	***45.1%***
Continuously-Eligible Total Paid Rx Claims	*3,541*	*2,523*	***40.3%***
Managed Care Plan Enrollees			
Total Eligible Beneficiaries	1,489,867	1,475,472	**1.0%**
Total Utilizing Beneficiaries	334,964	245,746	**36.3%**
Total Paid Rx Claims	859,385	647,698	**32.7%**
Average Paid Rx Claims per Eligible Beneficiary	0.58	0.44	**31.4%**
Average Paid Rx Claims per Utilizing Beneficiary	2.57	2.64	**-2.7%**
Continuously-Eligible Total Eligible Beneficiaries	*1,223,871*	*1,198,900*	***2.1%***
Continuously-Eligible Total Utilizing Beneficiaries	*163,100*	*112,783*	***44.6%***
Continuously-Eligible Total Paid Rx Claims	*288,805*	*211,060*	***36.8%***

Table 1.4 shows pharmacy utilization within the **Seniors and Persons with Disabilities (SPD)** population, which consists of the following SPD aid codes: 10, 13, 14, 16, 17, 1E, 1H, 20, 23, 24, 26, 27, 2E, 2H, 36, 60, 63, 64, 66, 67, 6A, 6C, 6E, 6G, 6H, 6J, 6N, 6P, 6R, 6V, 6W, 6X, 6Y, C1, C2, C3, C4, C7, C8, D2, D3, D4, D5, D6, and D7. Continuous eligibility is plan-specific and is measured from October 1, 2021 – December 1, 2021.

Among the total utilizing beneficiaries in the SPD population, 54% of FFS enrollees and 67% of MCP enrollees were continuously eligible within the same plan during 2021 Q4.

Table 1.4: Global Medi-Cal Pharmacy Utilization Measures for the SPD Population			
Category	**Current Quarter 2021 Q4**	**Prior-Year Quarter 2020 Q4**	**% Change from *Prior Year***
Total Eligible Beneficiaries	2,512,737	2,508,056	**0.2%**
Total Utilizing Beneficiaries	944,174	947,397	**-0.3%**
Total Paid Rx Claims	7,354,769	7,606,234	**-3.3%**
Average Paid Rx Claims per Eligible Beneficiary	2.93	3.03	**-3.5%**
Average Paid Rx Claims per Utilizing Beneficiary	7.79	8.03	**-3.0%**
Continuously-Eligible Total Eligible Beneficiaries	*2,125,640*	*2,124,503*	***0.1%***
Continuously-Eligible Total Utilizing Beneficiaries	*629,655*	*643,015*	***-2.1%***
Continuously-Eligible Total Paid Rx Claims	*4,894,484*	*5,159,912*	***-5.1%***
Fee-for-Service Enrollees			
Total Eligible Beneficiaries	493,549	507,630	**-2.8%**
Total Utilizing Beneficiaries	82,682	90,526	**-8.7%**
Total Paid Rx Claims	394,635	435,567	**-9.4%**
Average Paid Rx Claims per Eligible Beneficiary	0.80	0.86	**-6.8%**
Average Paid Rx Claims per Utilizing Beneficiary	4.77	4.81	**-0.8%**
Continuously-Eligible Total Eligible Beneficiaries	*382,635*	*395,248*	***-3.2%***
Continuously-Eligible Total Utilizing Beneficiaries	*45,045*	*49,896*	***-9.7%***
Continuously-Eligible Total Paid Rx Claims	*121,273*	*134,739*	***-10.0%***
Managed Care Plan Enrollees			
Total Eligible Beneficiaries	2,046,461	2,027,675	**0.9%**
Total Utilizing Beneficiaries	865,996	861,784	**0.5%**
Total Paid Rx Claims	6,963,866	7,181,740	**-3.0%**
Average Paid Rx Claims per Eligible Beneficiary	3.40	3.54	**-3.9%**
Average Paid Rx Claims per Utilizing Beneficiary	8.04	8.33	**-3.5%**
Continuously-Eligible Total Eligible Beneficiaries	*1,708,580*	*1,676,699*	***1.9%***
Continuously-Eligible Total Utilizing Beneficiaries	*576,862*	*584,186*	***-1.3%***
Continuously-Eligible Total Paid Rx Claims	*2,310,407*	*2,428,038*	***-4.8%***

Table 1.5 shows pharmacy utilization within the **Other Populations (OTHER)** population, which consists of all aid codes not categorized under ACA, OTLIC, or SPD. Continuous eligibility is plan-specific and is measured from October 1, 2021 – December 1, 2021.

Among the total utilizing beneficiaries in the OTHER population, 43% of FFS enrollees and 52% of MCP enrollees were continuously eligible within the same plan during 2021 Q4.

Table 1.5: Global Medi-Cal Pharmacy Utilization Measures for the OTHER Population			
Category	**Current Quarter 2021 Q4**	**Prior-Year Quarter 2020 Q4**	**% Change from *Prior Year***
Total Eligible Beneficiaries	7,718,793	7,165,216	**7.7%**
Total Utilizing Beneficiaries	2,056,276	1,625,584	**26.5%**
Total Paid Rx Claims	7,654,330	6,384,523	**19.9%**
Average Paid Rx Claims per Eligible Beneficiary	0.99	0.89	**11.3%**
Average Paid Rx Claims per Utilizing Beneficiary	3.72	3.93	**-5.2%**
Continuously-Eligible Total Eligible Beneficiaries	*6,297,688*	*5,815,811*	***8.3%***
Continuously-Eligible Total Utilizing Beneficiaries	*1,078,678*	*841,420*	***28.2%***
Continuously-Eligible Total Paid Rx Claims	*5,077,908*	*4,236,951*	***19.8%***
Fee-for-Service Enrollees			
Total Eligible Beneficiaries	1,712,056	1,547,863	**10.6%**
Total Utilizing Beneficiaries	228,937	200,659	**14.1%**
Total Paid Rx Claims	694,813	612,210	**13.5%**
Average Paid Rx Claims per Eligible Beneficiary	0.41	0.40	**2.6%**
Average Paid Rx Claims per Utilizing Beneficiary	3.03	3.05	**-0.5%**
Continuously-Eligible Total Eligible Beneficiaries	*1,102,670*	*952,045*	***15.8%***
Continuously-Eligible Total Utilizing Beneficiaries	*98,216*	*80,830*	***21.5%***
Continuously-Eligible Total Paid Rx Claims	*205,761*	*173,104*	***18.9%***
Managed Care Plan Enrollees			
Total Eligible Beneficiaries	6,149,557	5,776,599	**6.5%**
Total Utilizing Beneficiaries	1,836,034	1,433,154	**28.1%**
Total Paid Rx Claims	6,960,309	5,773,884	**20.5%**
Average Paid Rx Claims per Eligible Beneficiary	1.13	1.00	**13.2%**
Average Paid Rx Claims per Utilizing Beneficiary	3.79	4.03	**-5.9%**
Continuously-Eligible Total Eligible Beneficiaries	*5,046,649*	*4,700,879*	***7.4%***
Continuously-Eligible Total Utilizing Beneficiaries	*958,627*	*740,196*	***29.5%***
Continuously-Eligible Total Paid Rx Claims	*2,310,444*	*1,922,991*	***20.1%***

Table 2.1 – 2.3. Pharmacy Utilization by Age Group in the Medi-Cal Population.

These tables present pharmacy utilization data in the Medi-Cal program broken out by age group, including the percent change from the prior-year quarter. Beneficiaries with enrollments in both FFS and MCP during the quarter may be counted in both **Table 2.2** and **Table 2.3**, as enrollment status may change.

Table 2.1: Pharmacy Utilization by Age Group for the Entire Medi-Cal Population

Age Group (years)	Current Quarter 2021 Q4 Total Paid Claims	Prior-Year Quarter 2020 Q4 Total Paid Claims	% Change from *Prior Year*	Current Quarter 2021 Q4 Total Utilizing Beneficiaries	Prior-Year Quarter 2020 Q4 Total Utilizing Beneficiaries	% Change from *Prior Year*
0 – 12	2,259,454	1,530,843	**47.6%**	863,281	597,721	**44.4%**
13 – 18	1,448,420	1,206,792	**20.0%**	480,209	373,636	**28.5%**
19 – 39	6,361,970	5,733,572	**11.0%**	1,584,708	1,345,625	**17.8%**
40 – 64	14,649,016	13,874,226	**5.6%**	1,883,641	1,699,012	**10.9%**
65+	2,774,025	2,661,475	**4.2%**	515,074	487,855	**5.6%**
Total*	27,492,887	25,006,908	**9.9%**	5,326,914	4,503,849	**18.3%**

* Unknowns represent less than 1% of total

Table 2.2: Pharmacy Utilization by Age Group for the Medi-Cal FFS Population Only

Age Group (years)	Current Quarter 2021 Q4 Total Paid Claims	Prior-Year Quarter 2020 Q4 Total Paid Claims	% Change from *Prior Year*	Current Quarter 2021 Q4 Total Utilizing Beneficiaries	Prior-Year Quarter 2020 Q4 Total Utilizing Beneficiaries	% Change from *Prior Year*
0 – 12	123,824	104,824	**18.1%**	48,280	39,215	**23.1%**
13 – 18	81,902	80,289	**2.0%**	21,732	19,728	**10.2%**
19 – 39	413,765	408,923	**1.2%**	135,245	130,178	**3.9%**
40 – 64	822,083	757,571	**8.5%**	182,071	162,797	**11.8%**
65+	208,837	196,947	**6.0%**	61,931	60,724	**2.0%**
Total*	1,650,413	1,548,554	**6.6%**	449,260	412,642	**8.9%**

* Unknowns represent less than 1% of total

Table 2.3: Pharmacy Utilization by Age Group for the Medi-Cal MCP Population Only

Age Group (years)	Current Quarter 2021 Q4 Total Paid Claims	Prior-Year Quarter 2020 Q4 Total Paid Claims	% Change from *Prior Year*	Current Quarter 2021 Q4 Total Utilizing Beneficiaries	Prior-Year Quarter 2020 Q4 Total Utilizing Beneficiaries	% Change from *Prior Year*
0 – 12	2,134,713	1,424,236	**49.9%**	817,785	560,434	**45.9%**
13 – 18	1,366,443	1,126,726	**21.3%**	459,435	354,853	**29.5%**
19 – 39	5,949,019	5,327,270	**11.7%**	1,457,193	1,222,792	**19.2%**
40 – 64	13,825,879	13,125,588	**5.3%**	1,711,523	1,548,025	**10.6%**
65+	2,564,746	2,465,745	**4.0%**	454,433	428,438	**6.1%**
Total*	25,840,800	23,469,565	**10.1%**	4,900,369	4,114,542	**19.1%**

* Unknowns represent less than 1% of total

Table 3. Top 20 Drug Therapeutic Categories in the Medi-Cal Population.

This table presents the top 20 drug therapeutic categories in the Medi-Cal program, by **total utilizing beneficiaries.** The current quarter is compared to the prior-year quarter in order to illustrate changes in utilization for these drugs. The prior-year quarter ranking of the drug therapeutic category is listed for reference.

Table 3: Top 20 Drug Therapeutic Categories by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population

Rank	Last Year Rank	Drug Therapeutic Category Description	Current Quarter 2021 Q4 Total Paid Claims	% Change from *Prior Year*	Current Quarter 2021 Q4 Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change from *Prior Year*
1	1	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	1,090,008	**9.4%**	852,697	16.0%	**-0.7%**
2	150	COVID-19 VACCINES	790,285	**> 100%**	695,508	13.1%	**> 100%**
3	2	ANTIHYPERLIPIDEMIC-HMGCOA REDUCTASE INHIB(STATINS)	1,013,660	**8.8%**	579,995	10.9%	**-1.0%**
4	4	VITAMIN D PREPARATIONS	842,090	**13.9%**	485,296	9.1%	**-0.3%**
5	10	PENICILLIN ANTIBIOTICS	507,905	**35.6%**	471,645	8.9%	**1.2%**
6	5	ANTIHISTAMINES - 2ND GENERATION	728,320	**11.1%**	469,174	8.8%	**-0.3%**
7	3	ANTICONVULSANTS	962,830	**2.8%**	448,761	8.4%	**-1.2%**
8	6	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	693,920	**15.3%**	437,604	8.2%	**0.1%**
9	9	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	761,309	**7.9%**	371,253	7.0%	**-0.7%**
10	7	PLATELET AGGREGATION INHIBITORS	626,069	**-2.5%**	354,128	6.7%	**-1.3%**
11	8	PROTON-PUMP INHIBITORS	599,566	**-0.5%**	350,771	6.6%	**-1.1%**
12	12	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	609,184	**8.2%**	349,266	6.6%	**-0.6%**
13	11	LAXATIVES AND CATHARTICS	502,098	**3.0%**	343,927	6.5%	**-0.8%**
14	13	ANTIHYPERTENSIVES, ACE INHIBITORS	572,352	**1.7%**	321,051	6.0%	**-1.0%**
15	15	TOPICAL ANTI-INFLAMMATORY STEROIDAL	373,366	**-2.3%**	297,634	5.6%	**-1.1%**
16	14	INFLUENZA VIRUS VACCINES	281,493	**-9.0%**	283,556	5.3%	**-1.7%**
17	17	CALCIUM CHANNEL BLOCKING AGENTS	491,765	**7.0%**	274,176	5.2%	**-0.6%**
18	19	ANALGESIC/ANTIPYRETICS,NON-SALICYLATE	294,727	**16.5%**	257,301	4.8%	**0.0%**
19	16	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS	421,937	**-6.0%**	257,283	4.8%	**-1.2%**
20	22	NASAL ANTI-INFLAMMATORY STEROIDS	332,105	**7.8%**	236,582	4.4%	**-0.3%**

Tables 4.1 – 4.4. Top 20 Drug Therapeutic Categories in the Continuously-Eligible Medi-Cal Population by Population Aid Code Group, Stratified by Program.

These tables present the top 20 drug therapeutic categories in the Medi-Cal program by **total continuously-eligible utilizing beneficiaries from each population aid code group, stratified by Medi-Cal program.** Mean days' supply per utilizing beneficiary is included for reference. Continuous eligibility is plan-specific and is measured from October 1, 2021 – December 1, 2021.

Table 4.1 presents the top 20 drug therapeutic categories in the **Affordable Care Act (ACA)** population, which consists of the following Adult Expansion aid codes: M1, M2, L1, and 7U.

Table 4.1: Top 20 Drug Therapeutic Categories by *Total Continuously-Eligible ACA Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program

		Current Quarter 2021 Q4				
		Mean Days' Supply per Utilizing Beneficiary		Total Continuously-Eligible Utilizing Beneficiaries		
Rank	Drug Therapeutic Category Description	FFS	MCP	All Medi-Cal	% FFS	% MCP
1	ANTIHYPERLIPIDEMIC-HMGCOA REDUCTASE INHIB(STATINS)	86	59	183,889	14.6%	15.1%
2	COVID-19 VACCINES	2	2	157,146	13.9%	12.7%
3	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	25	30	149,493	12.9%	12.1%
4	ANTICONVULSANTS	57	43	124,090	9.9%	10.1%
5	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	56	45	112,327	6.3%	9.3%
6	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	85	61	109,136	11.6%	8.8%
7	ANTIHYPERTENSIVES, ACE INHIBITORS	86	62	104,894	10.3%	8.5%
8	PROTON-PUMP INHIBITORS	64	52	96,168	7.7%	7.9%
9	VITAMIN D PREPARATIONS	78	49	92,118	1.9%	7.9%
10	CALCIUM CHANNEL BLOCKING AGENTS	80	57	83,665	6.7%	6.8%
11	BETA-ADRENERGIC BLOCKING AGENTS	87	53	70,518	5.1%	5.8%
12	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	40	30	69,030	4.7%	5.7%
13	PLATELET AGGREGATION INHIBITORS	90	59	66,108	5.1%	5.4%
14	ANTIHISTAMINES - 2ND GENERATION	61	42	65,107	3.2%	5.5%
15	BLOOD SUGAR DIAGNOSTICS	35	52	62,829	< 1.0%	5.4%
16	ANTIHYPERTENSIVES, ANGIOTENSIN RECEPTOR ANTAGONIST	94	58	62,716	4.4%	5.2%
17	INSULINS	80	45	62,475	8.1%	4.9%
18	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS	12	24	56,448	3.9%	4.6%
19	THYROID HORMONES	87	57	56,054	3.7%	4.6%
20	PENICILLIN ANTIBIOTICS	12	19	53,035	4.9%	4.3%

Table 4.2 presents the top 20 drug therapeutic categories in the **Optional Targeted Low Income Children (OTLIC)** population, which consists of the following OTLIC aid codes: 2P, 2R, 2S, 2T, 2U, 5C, 5D, E2, E5, E6, E7, H1, H2, H3, H4, H5, M5, T0, T1, T2, T3, T4, T5, T6, T7, T8, and T9.

Table 4.2: Top 20 Drug Therapeutic Categories by *Total Continuously-Eligible OTLIC Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program

		Current Quarter 2021 Q4				
		Mean Days' Supply per Utilizing Beneficiary		Total Continuously-Eligible Utilizing Beneficiaries		
Rank	Drug Therapeutic Category Description	FFS	MCP	All Medi-Cal	% FFS	% MCP
1	COVID-19 VACCINES	2	2	32,707	15.8%	19.6%
2	ANTIHISTAMINES - 2ND GENERATION	56	35	18,232	6.0%	11.0%
3	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	37	33	15,780	13.9%	9.4%
4	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	16	25	15,596	8.9%	9.3%
5	PENICILLIN ANTIBIOTICS	17	19	14,077	12.8%	8.3%
6	NASAL ANTI-INFLAMMATORY STEROIDS	48	43	9,500	3.8%	5.7%
7	TOPICAL ANTI-INFLAMMATORY STEROIDAL	48	29	8,035	3.8%	4.8%
8	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	49	43	7,859	4.8%	4.7%
9	TOPICAL ANTIBIOTICS	41	33	7,132	2.3%	4.3%
10	GLUCOCORTICOIDS, ORALLY INHALED	72	43	6,920	5.2%	4.1%
11	ANALGESIC/ANTIPYRETICS,NON-SALICYLATE	14	20	6,191	5.0%	3.7%
12	VITAMIN D PREPARATIONS	96	45	6,039	< 1.0%	3.7%
13	CONTRACEPTIVES,ORAL	76	69	5,301	2.9%	3.2%
14	GLUCOCORTICOIDS	15	30	5,217	5.4%	3.1%
15	MACROLIDE ANTIBIOTICS	15	28	5,147	4.0%	3.1%
16	LEUKOTRIENE RECEPTOR ANTAGONISTS	47	39	5,126	2.9%	3.1%
17	ANTIEMETIC/ANTIVERTIGO AGENTS	8	12	4,945	3.9%	3.0%
18	ANTIHISTAMINES - 1ST GENERATION	34	33	4,670	2.9%	2.8%
19	KERATOLYTICS	56	36	4,516	< 1.0%	2.7%
20	VITAMIN A DERIVATIVES	50	36	4,416	1.3%	2.7%

Table 4.3 presents the top 20 drug therapeutic categories in the **Seniors and Persons with Disabilities (SPD)** population, which consists of the following SPD aid codes: 10, 13, 14, 16, 17, 1E, 1H, 20, 23, 24, 26, 27, 2E, 2H, 36, 60, 63, 64, 66, 67, 6A, 6C, 6E, 6G, 6H, 6J, 6N, 6P, 6R, 6V, 6W, 6X, 6Y, C1, C2, C3, C4, C7, C8, D2, D3, D4, D5, D6, and D7.

Table 4.3: Top 20 Drug Therapeutic Categories by *Total Continuously-Eligible SPD Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program

		Current Quarter 2021 Q4				
		Mean Days' Supply per Utilizing Beneficiary		Total Continuously-Eligible Utilizing Beneficiaries		
Rank	Drug Therapeutic Category Description	FFS	MCP	All Medi-Cal	% FFS	% MCP
1	VITAMIN D PREPARATIONS	57	45	118,666	7.0%	19.9%
2	PLATELET AGGREGATION INHIBITORS	74	53	112,430	21.1%	17.7%
3	ANTICONVULSANTS	54	47	105,011	14.4%	16.8%
4	ANTIHYPERLIPIDEMIC-HMGCOA REDUCTASE INHIB(STATINS)	57	56	86,798	5.2%	14.4%
5	LAXATIVES AND CATHARTICS	47	36	78,345	18.4%	12.0%
6	ANTIHISTAMINES - 2ND GENERATION	57	42	67,977	14.7%	10.6%
7	ANTIPSYCHOTIC,ATYPICAL,DOPAMINE, SEROTONIN ANTAGNST	49	51	61,669	6.2%	10.0%
8	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	49	46	49,874	3.8%	8.2%
9	PROTON-PUMP INHIBITORS	53	51	48,899	4.2%	8.0%
10	CALCIUM REPLACEMENT	71	44	47,859	4.1%	7.9%
11	CALCIUM CHANNEL BLOCKING AGENTS	57	55	46,986	2.8%	7.8%
12	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	30	34	42,479	1.9%	7.1%
13	ANTIHYPERTENSIVES, ACE INHIBITORS	61	57	40,935	2.6%	6.8%
14	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	61	57	40,810	2.3%	6.8%
15	BETA-ADRENERGIC BLOCKING AGENTS	58	51	39,635	3.0%	6.5%
16	BLOOD SUGAR DIAGNOSTICS	12	48	37,552	< 1.0%	6.4%
17	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	45	37	36,280	3.4%	5.9%
18	IRON REPLACEMENT	56	47	32,015	8.3%	4.9%
19	ANTIHISTAMINES - 1ST GENERATION	41	37	31,024	4.2%	5.0%
20	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS	23	34	31,003	1.7%	5.2%

Table 4.4 presents the top 20 drug therapeutic categories in the **Other Populations (OTHER)** population, which consists of all aid codes not categorized under ACA, OTLIC, or SPD.

Table 4.4: Top 20 Drug Therapeutic Categories by *Total Continuously-Eligible OTHER Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program

		Current Quarter 2021 Q4				
		Mean Days' Supply per Utilizing Beneficiary		Total Continuously-Eligible Utilizing Beneficiaries		
Rank	Drug Therapeutic Category Description	FFS	MCP	All Medi-Cal	% FFS	% MCP
1	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	22	31	146,768	13.4%	13.7%
2	COVID-19 VACCINES	2	2	118,122	12.2%	10.9%
3	PENICILLIN ANTIBIOTICS	14	22	91,978	6.5%	8.7%
4	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	38	37	89,787	5.5%	8.6%
5	ANTIHISTAMINES - 2ND GENERATION	65	40	85,073	3.9%	8.4%
6	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	56	48	64,810	5.1%	6.1%
7	ANTIHYPERLIPIDEMIC-HMGCOA REDUCTASE INHIB(STATINS)	90	62	57,905	6.8%	5.3%
8	ANTICONVULSANTS	58	50	57,244	5.3%	5.3%
9	VITAMIN D PREPARATIONS	80	49	57,017	1.4%	5.7%
10	ANALGESIC/ANTIPYRETICS,NON-SALICYLATE	18	29	52,051	4.5%	4.7%
11	TOPICAL ANTI-INFLAMMATORY STEROIDAL	43	32	48,818	2.9%	4.7%
12	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	87	65	45,727	6.9%	4.0%
13	PROTON-PUMP INHIBITORS	67	53	45,712	4.5%	4.3%
14	NASAL ANTI-INFLAMMATORY STEROIDS	65	45	42,645	2.4%	4.2%
15	GLUCOCORTICOIDS	19	38	40,112	2.8%	3.8%
16	ANTIEMETIC/ANTIVERTIGO AGENTS	15	17	39,829	3.3%	3.7%
17	LAXATIVES AND CATHARTICS	49	34	39,285	4.0%	3.6%
18	CONTRACEPTIVES,ORAL	109	73	38,288	3.8%	3.5%
19	ANTIHISTAMINES - 1ST GENERATION	37	36	38,248	2.6%	3.7%
20	ANTIHYPERTENSIVES, ACE INHIBITORS	90	64	37,664	5.1%	3.4%

Table 5. Top 20 Drugs in the Medi-Cal Population.

This table presents the top 20 drugs in the Medi-Cal program by **total utilizing beneficiaries.** The current quarter is compared to the prior-year quarter in order to illustrate changes in utilization for these drugs. The prior-year quarter ranking of each drug is listed for reference.

Table 5: Top 20 Drugs by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population							
Rank	Last Year Rank	Drug Description	Current Quarter 2021 Q4 Total Paid Claims	% Change from *Prior Year*	Current Quarter 2021 Q4 Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change from *Prior Year*
1	1	IBUPROFEN	769,216	**12.9%**	634,262	11.9%	**-0.2%**
2	3	ALBUTEROL SULFATE	694,442	**16.1%**	440,219	8.3%	**0.2%**
3	2	ATORVASTATIN CALCIUM	757,882	**12.7%**	432,967	8.1%	**-0.5%**
4	626	COVID-19 VACC, MRNA (PFIZER)/PF	469,927	**> 100%**	406,411	7.6%	**> 100%**
5	5	METFORMIN HCL	609,185	**8.2%**	349,267	6.6%	**-0.6%**
6	10	AMOXICILLIN	368,772	**39.8%**	340,908	6.4%	**1.0%**
7	4	ASPIRIN	578,908	**-1.3%**	331,870	6.2%	**-1.1%**
8	6	CHOLECALCIFEROL (VITAMIN D3)	558,426	**17.5%**	331,219	6.2%	**-0.1%**
9	8	FLUTICASONE PROPIONATE	408,927	**8.9%**	286,404	5.4%	**-0.3%**
10	7	LORATADINE	440,408	**4.4%**	280,151	5.3%	**-0.5%**
11	13	ACETAMINOPHEN	300,572	**18.1%**	262,898	4.9%	**0.1%**
12	9	LISINOPRIL	466,154	**4.0%**	260,742	4.9%	**-0.7%**
13	12	AMLODIPINE BESYLATE	427,684	**7.5%**	239,447	4.5%	**-0.5%**
14	11	OMEPRAZOLE	400,783	**-3.1%**	235,642	4.4%	**-0.9%**
15	14	BLOOD SUGAR DIAGNOSTIC	390,796	**4.5%**	228,301	4.3%	**-0.5%**
16	15	GABAPENTIN	437,506	**2.9%**	222,615	4.2%	**-0.6%**
17	1774	COVID-19 VACC,MRNA (MODERNA)/PF	216,655	**> 100%**	212,313	4.0%	**> 100%**
18	16	HYDROCODONE/ ACETAMINOPHEN	311,644	**-5.4%**	184,756	3.5%	**-0.8%**
19	17	LEVOTHYROXINE SODIUM	352,340	**4.2%**	181,694	3.4%	**-0.5%**
20	20	LOSARTAN POTASSIUM	313,529	**11.1%**	176,021	3.3%	**-0.2%**

Tables 6.1 – 6.4. Top 20 Drugs in the Medi-Cal Population, by Population Aid Code Group and Program.

These tables present utilization of the top 20 drugs in the Medi-Cal program by **total continuously-eligible utilizing beneficiaries from each population aid code group, stratified by Medi-Cal program.** Mean days' supply per utilizing beneficiary is included for reference. Continuous eligibility is plan-specific and is measured from October 1, 2021 – December 1, 2021.

Table 6.1 presents the top 20 drugs in the **Affordable Care Act (ACA)** population, which consists of the following Adult Expansion aid codes: M1, M2, L1, and 7U.

Table 6.1: Top 20 Drugs by *Total Continuously-Eligible ACA Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program

		Current Quarter 2021 Q4				
		Mean Days' Supply per Utilizing Beneficiary		Total Continuously-Eligible Utilizing Beneficiaries		
Rank	Drug Description	FFS	MCP	All Medi-Cal	% FFS	% MCP
1	ATORVASTATIN CALCIUM	86	62	138,494	11.3%	11.3%
2	METFORMIN HCL	85	63	109,137	11.6%	8.8%
3	IBUPROFEN	20	26	94,209	9.3%	7.6%
4	LISINOPRIL	80	65	86,400	8.5%	7.0%
5	COVID-19 VACC, MRNA (PFIZER)/PF	1	1	85,403	7.4%	6.9%
6	AMLODIPINE BESYLATE	79	60	74,271	5.9%	6.1%
7	GABAPENTIN	54	47	69,460	5.6%	5.6%
8	ALBUTEROL SULFATE	39	34	68,653	4.7%	5.6%
9	COVID-19 VACC,MRNA (MODERNA)/PF	2	2	68,354	6.1%	5.5%
10	OMEPRAZOLE	67	52	64,756	4.4%	5.4%
11	BLOOD SUGAR DIAGNOSTIC	35	54	62,921	< 1.0%	5.4%
12	CHOLECALCIFEROL (VITAMIN D3)	46	46	60,120	< 1.0%	5.2%
13	ASPIRIN	93	61	57,313	4.1%	4.7%
14	LOSARTAN POTASSIUM	94	62	56,853	4.1%	4.7%
15	LEVOTHYROXINE SODIUM	87	62	53,730	3.7%	4.4%
16	FLUTICASONE PROPIONATE	58	43	48,225	2.8%	4.0%
17	HYDROCODONE/ACETAMINOPHEN	11	28	41,561	2.9%	3.4%
18	LORATADINE	61	46	39,033	2.0%	3.3%
19	HYDROCHLOROTHIAZIDE	80	66	38,993	3.1%	3.2%
20	SERTRALINE HCL	56	48	38,299	2.3%	3.2%

Table 6.2 presents the top 20 drugs in the **Optional Targeted Low Income Children (OTLIC)** population, which consists of the following OTLIC aid codes: 2P, 2R, 2S, 2T, 2U, 5C, 5D, E2, E5, E6, E7, H1, H2, H3, H4, H5, M5, T0, T1, T2, T3, T4, T5, T6, T7, T8, and T9.

Table 6.2: Top 20 Drugs by *Total Continuously-Eligible OTLIC Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program

		Current Quarter 2021 Q4				
		Mean Days' Supply per Utilizing Beneficiary		Total Continuously-Eligible Utilizing Beneficiaries		
Rank	Drug Description	FFS	MCP	All Medi-Cal	% FFS	% MCP
1	COVID-19 VAC, TRIS(PFIZER)/PF	2	2	17,576	8.4%	10.5%
2	ALBUTEROL SULFATE	36	32	15,901	13.4%	9.5%
3	IBUPROFEN	14	25	14,290	8.4%	8.6%
4	COVID-19 VACC, MRNA(PFIZER)/PF	2	2	13,428	5.9%	8.1%
5	FLUTICASONE PROPIONATE	57	42	13,034	6.8%	7.9%
6	AMOXICILLIN	16	21	11,286	9.7%	6.7%
7	LORATADINE	56	37	9,813	4.5%	5.9%
8	CETIRIZINE HCL	55	33	8,115	1.4%	4.9%
9	ACETAMINOPHEN	14	20	6,292	5.0%	3.7%
10	MONTELUKAST SODIUM	47	39	5,123	2.9%	3.1%
11	AZITHROMYCIN	9	28	5,009	3.7%	3.0%
12	CHOLECALCIFEROL (VITAMIN D3)	93	40	4,913	< 1.0%	3.0%
13	BENZOYL PEROXIDE	50	36	4,460	< 1.0%	2.7%
14	CLINDAMYCIN PHOSPHATE	54	39	4,445	1.2%	2.7%
15	CEPHALEXIN	20	22	3,744	2.6%	2.2%
16	TRIAMCINOLONE ACETONIDE	62	31	3,738	2.1%	2.2%
17	TRETINOIN	50	29	3,539	1.3%	2.1%
18	PROMETHAZINE/ DEXTROMETHORPHAN	15	64	3,522	2.4%	2.1%
19	ONDANSETRON	7	12	3,287	2.4%	2.0%
20	POLYETHYLENE GLYCOL 3350	55	33	3,049	1.5%	1.8%

Table 6.3 presents the top 20 drugs in the **Seniors and Persons with Disabilities (SPD)** population, which consists of the following SPD aid codes: 10, 13, 14, 16, 17, 1E, 1H, 20, 23, 24, 26, 27, 2E, 2H, 36, 60, 63, 64, 66, 67, 6A, 6C, 6E, 6G, 6H, 6J, 6N, 6P, 6R, 6V, 6W, 6X, 6Y, C1, C2, C3, C4, C7, C8, D2, D3, D4, D5, D6, and D7.

Table 6.3: Top 20 Drugs by *Total Continuously-Eligible SPD Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program

		Current Quarter 2021 Q4				
		Mean Days' Supply per Utilizing Beneficiary		Total Continuously-Eligible Utilizing Beneficiaries		
Rank	Drug Description	FFS	MCP	All Medi-Cal	% FFS	% MCP
1	ASPIRIN	74	52	108,890	20.9%	17.1%
2	CHOLECALCIFEROL (VITAMIN D3)	58	45	80,118	< 1.0%	13.8%
3	ATORVASTATIN CALCIUM	56	57	63,616	3.9%	10.6%
4	LORATADINE	57	45	46,032	11.5%	7.0%
5	DOCUSATE SODIUM	48	40	43,561	12.9%	6.5%
6	METFORMIN HCL	61	57	40,810	2.3%	6.8%
7	AMLODIPINE BESYLATE	57	55	40,520	2.4%	6.7%
8	ERGOCALCIFEROL (VITAMIN D2)	57	44	40,141	6.4%	6.4%
9	GABAPENTIN	50	46	39,697	3.0%	6.5%
10	BLOOD SUGAR DIAGNOSTIC	12	47	37,629	< 1.0%	6.5%
11	ALBUTEROL SULFATE	43	37	35,570	3.0%	5.9%
12	LISINOPRIL	61	59	31,615	2.0%	5.3%
13	FERROUS SULFATE	56	47	31,246	8.3%	4.7%
14	OMEPRAZOLE	52	48	30,430	1.3%	5.1%
15	LOSARTAN POTASSIUM	70	58	26,800	1.2%	4.5%
16	FOLIC ACID	54	46	26,155	8.2%	3.9%
17	LEVOTHYROXINE SODIUM	56	56	25,367	2.7%	4.1%
18	CALCIUM CARBONATE/VITAMIN D3	56	47	25,235	< 1.0%	4.4%
19	HYDROCODONE/ACETAMINOPHEN	22	36	23,695	1.2%	4.0%
20	IBUPROFEN	25	30	23,570	1.2%	3.9%

Table 6.4 presents the top 20 drugs in the **Other Populations (OTHER)** population, which consists of all aid codes not categorized under ACA, OTLIC, or SPD.

Table 6.4: Top 20 Drug by *Total Continuously-Eligible OTHER Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program

		Current Quarter 2021 Q4				
		Mean Days' Supply per Utilizing Beneficiary		Total Continuously-Eligible Utilizing Beneficiaries		
Rank	Drug Description	FFS	MCP	All Medi-Cal	% FFS	% MCP
1	IBUPROFEN	18	30	118,081	11.0%	11.0%
2	ALBUTEROL SULFATE	37	37	91,169	5.6%	8.7%
3	AMOXICILLIN	13	25	71,263	4.7%	6.8%
4	COVID-19 VACC, MRNA(PFIZER)/PF	2	2	58,637	6.7%	5.3%
5	FLUTICASONE PROPIONATE	66	44	57,073	3.4%	5.5%
6	ACETAMINOPHEN	18	29	52,936	4.5%	4.8%
7	LORATADINE	65	42	47,654	2.6%	4.7%
8	METFORMIN HCL	87	65	45,727	6.9%	4.0%
9	ATORVASTATIN CALCIUM	91	63	43,963	5.1%	4.0%
10	CHOLECALCIFEROL (VITAMIN D3)	74	42	38,093	< 1.0%	3.9%
11	CETIRIZINE HCL	65	38	35,417	1.3%	3.5%
12	COVID-19 VAC, TRIS(PFIZER)/PF	2	2	33,803	3.6%	3.3%
13	FERROUS SULFATE	80	55	33,301	4.5%	2.9%
14	AZITHROMYCIN	8	37	33,115	2.1%	3.2%
15	OMEPRAZOLE	67	51	32,134	2.9%	3.0%
16	LISINOPRIL	86	66	31,549	4.1%	2.8%
17	LEVOTHYROXINE SODIUM	86	64	28,565	2.6%	2.7%
18	CEPHALEXIN	12	29	26,817	2.6%	2.5%
19	HYDROCODONE/ACETAMINOPHEN	8	32	26,491	2.1%	2.5%
20	BLOOD SUGAR DIAGNOSTIC	42	53	26,378	0.2%	2.7%

ANNUAL SUMMARY
GLOBAL MEDI-CAL DRUG USE REVIEW
CALENDAR YEAR 2021 (JANUARY – DECEMBER 2021)

Executive Summary

The Global DUR annual report provides information on retrospective drug utilization for all pharmacy claims processed by Medi-Cal. For this report, the retrospective data cover the calendar year of 2021.

Table 1 provides a summary of pharmacy utilization during calendar year 2021 for the entire Medi-Cal program, as well as stratified by beneficiaries enrolled in Medi-Cal fee-for-service (FFS) and Medi-Cal managed care plans (MCPs). In 2021, approximately 51% of eligible Medi-Cal enrollees had a paid pharmacy claim through the Medi-Cal program, including 21% of eligible Medi-Cal FFS enrollees and 56% of Medi-Cal MCP enrollees. Among all Medi-Cal beneficiaries with a paid pharmacy claim through the Medi-Cal program in 2021, only 9% were FFS enrollees and 92% were MCP enrollees (numbers add up to more than 100% due to 1% of beneficiaries being enrolled in both programs during 2021).

In 2021, FFS enrollees were approximately 23% of eligible Medi-Cal beneficiaries, 9% of utilizing beneficiaries, and 6% of total paid pharmacy claims. For 2021, the MCP enrollees had a higher average number of paid pharmacy claims per eligible beneficiary than the FFS enrollees (4.36 vs. 1.04) and a higher average number of paid pharmacy claims per utilizing beneficiary (7.71 vs. 5.00), which may help explain the higher percentage of paid pharmacy claims by MCP enrollees.

As shown in **Table 2**, total paid pharmacy claims increased among all age groups from the prior year (2020), with the exception of the 0 – 12 year age group, which posted an 8% decrease in total paid pharmacy claims and a slight (less than 1%) decrease in total utilizing beneficiaries.

In this report, two tables highlight utilization among the top 20 drug therapeutic drug categories (**Table 3**) and top 20 drugs (**Table 5**) among all Medi-Cal beneficiaries, in comparision to the prior year. Two additional tables show the top 20 drug therapeutic drug categories (**Table 4**) and top 20 drugs (**Table 6**) along with the corresponding percentages among the FFS and MCP enrollee populations.

Table 4 suggests more utilizing beneficiaries in the MCP population had paid claims for VITAMIN D PREPARATIONS, NASAL ANTI-INFLAMMATORY STEROIDS, and ANTIHISTAMINES – 2ND GENERATION than in the FFS population. Similarly, **Table 6** suggests more utilizing beneficiaries in the MCP population had paid claims for CHOLECALCIFEROL (VITAMIN D3), FLUTICASONE PROPIONATE, and BLOOD SUGAR DIAGNOSTIC than in the FFS population.

Table 1. Summary of Global Medi-Cal Pharmacy Utilization.

This table shows pharmacy utilization in the Medi-Cal program, including the percent change from the prior year. Beneficiaries with enrollments in both FFS and MCP during the year may be counted twice (represents 1% of utilizing beneficiaries).

Table 1: Pharmacy Utilization Measures for the Entire Medi-Cal Population			
Category	**Current Year 2021**	**Prior Year 2020**	**% Change from *Prior Year***
Total Eligible Beneficiaries	27,522,635	26,125,306	**5.3%**
Total Utilizing Beneficiaries	14,087,829	12,619,478	**11.6%**
Total Paid Rx Claims	106,293,930	102,181,027	**4.0%**
Average Paid Rx Claims per Eligible Beneficiary	3.86	3.91	**-1.3%**
Average Paid Rx Claims per Utilizing Beneficiary	7.55	8.10	**-6.8%**
Fee-for-Service Enrollees			
Total Eligible Beneficiaries	6,278,486	6,603,801	**-4.9%**
Total Utilizing Beneficiaries	1,305,672	1,291,053	**1.1%**
Total Paid Rx Claims	6,526,878	6,305,899	**3.5%**
Average Paid Rx Claims per Eligible Beneficiary	1.04	0.95	**8.9%**
Average Paid Rx Claims per Utilizing Beneficiary	5.00	4.88	**2.3%**
Managed Care Plan Enrollees			
Total Eligible Beneficiaries	22,899,187	21,650,169	**5.8%**
Total Utilizing Beneficiaries	12,931,324	11,512,635	**12.3%**
Total Paid Rx Claims	99,740,459	95,953,551	**3.9%**
Average Paid Rx Claims per Eligible Beneficiary	4.36	4.43	**-1.7%**
Average Paid Rx Claims per Utilizing Beneficiary	7.71	8.33	**-7.5%**

Table 2. Pharmacy Utilization by Age Group in the Medi-Cal Population.

This table presents pharmacy utilization data in the Medi-Cal program, broken out by age group, including the percent change from the prior year.

Table 2: Pharmacy Utilization by Age Group for the Entire Medi-Cal Population						
Age Group (years)	**Current Year 2021 Total Paid Claims**	**Prior Year 2020 Total Paid Claims**	**% Change from *Prior Year***	**Current Year 2021 Total Utilizing Beneficiaries**	**Prior Year 2020 Total Utilizing Beneficiaries**	**% Change from *Prior Year***
0 – 12	7,440,019	8,099,227	**-8.1%**	2,280,998	2,286,437	**-0.2%**
13 – 18	5,734,297	5,058,318	**13.4%**	1,413,761	1,134,713	**24.6%**
19 – 39	25,002,859	22,779,515	**9.8%**	4,298,494	3,641,045	**18.1%**
40 – 64	57,472,236	55,828,504	**2.9%**	4,783,862	4,308,840	**11.0%**
65+	10,644,511	10,415,459	**2.2%**	1,310,712	1,248,440	**5.0%**
Total*	106,293,930	102,181,027	**4.0%**	14,087,829	12,619,478	**11.6%**

* Unknowns represent less than 1% of total

Table 3. Top 20 Drug Therapeutic Categories in the Medi-Cal Population.

This table presents utilization of the top 20 drug therapeutic categories in the Medi-Cal program, by **total utilizing beneficiaries.** The current year is compared to the prior year in order to illustrate changes in utilization for these drugs. The prior year ranking of the drug therapeutic category is listed for reference.

Table 3: Top 20 Drug Therapeutic Categories by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population

Rank	Last Year Rank	Drug Therapeutic Category Description	Current Year 2021 Total Paid Claims	% Change from *Prior Year*	Current Year 2021 Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries *Prior Year*
1	1	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	3,115,562	-27.7%	1,837,218	13.0%	-8.2%
2	150	COVID-19 VACCINES	2,119,333	> 100%	1,248,734	8.9%	> 100%
3	2	PENICILLIN ANTIBIOTICS	1,241,801	-31.4%	1,033,731	7.3%	-4.9%
4	3	ANTIHISTAMINES - 2ND GENERATION	2,061,689	-30.3%	824,521	5.9%	-4.4%
5	7	VITAMIN D PREPARATIONS	2,478,148	-12.2%	771,261	5.5%	-2.6%
6	4	ANTIHYPERLIPIDEMIC-HMGCOA REDUCTASE INHIB(STATINS)	2,874,037	-23.3%	755,435	5.4%	-4.3%
7	8	TOPICAL ANTI-INFLAMMATORY STEROIDAL	1,204,545	-22.7%	747,865	5.3%	-2.7%
8	9	LAXATIVES AND CATHARTICS	1,467,041	-23.3%	720,773	5.1%	-2.6%
9	5	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	1,792,759	-32.1%	712,076	5.1%	-4.3%
10	6	ANTICONVULSANTS	2,875,159	-24.6%	647,563	4.6%	-3.6%
11	11	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS	1,317,647	-26.8%	605,999	4.3%	-2.5%
12	10	PROTON-PUMP INHIBITORS	1,827,638	-24.4%	588,337	4.2%	-2.9%
13	19	ANTIEMETIC/ANTIVERTIGO AGENTS	822,632	-17.0%	561,669	4.0%	-1.5%
14	13	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	2,219,107	-20.8%	532,377	3.8%	-2.8%
15	14	ANALGESIC/ANTIPYRETICS,NON-SALICYLATE	771,946	-29.1%	526,378	3.7%	-2.5%
16	12	PLATELET AGGREGATION INHIBITORS	1,922,602	-26.3%	499,028	3.5%	-3.1%
17	21	CEPHALOSPORIN ANTIBIOTICS - 1ST GENERATION	567,617	-20.8%	483,049	3.4%	-1.5%
18	17	ANTIHISTAMINES - 1ST GENERATION	1,060,255	-25.0%	473,198	3.4%	-2.2%
19	16	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	1,750,782	-23.1%	452,454	3.2%	-2.6%
20	18	NASAL ANTI-INFLAMMATORY STEROIDS	960,928	-31.2%	441,194	3.1%	-2.4%

Table 4. Top 20 Drug Therapeutic Categories in the Medi-Cal Population, by Program.
This table presents utilization of the top 20 drug therapeutic categories in the Medi-Cal program, by **total utilizing beneficiaries stratified by Medi-Cal program.**

Table 4: Top 20 Drug Therapeutic Categories by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program

		Current Year 2021					
		Total Paid Claims			Total Utilizing Beneficiaries		
Rank	Drug Therapeutic Category Description	All Medi-Cal	% FFS	% MCP	All Medi-Cal	% FFS	% MCP
1	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	3,115,562	3.3%	2.9%	1,837,218	12.3%	13.0%
2	COVID-19 VACCINES	2,119,333	2.5%	2.0%	1,248,734	7.7%	8.9%
3	PENICILLIN ANTIBIOTICS	1,241,801	1.4%	1.2%	1,033,731	6.2%	7.4%
4	ANTIHISTAMINES - 2ND GENERATION	2,061,689	1.9%	1.9%	824,521	4.0%	6.0%
5	VITAMIN D PREPARATIONS	2,478,148	0.9%	2.4%	771,261	1.9%	5.8%
6	ANTIHYPERLIPIDEMIC-HMGCOA REDUCTASE INHIB(STATINS)	2,874,037	2.5%	2.7%	755,435	5.2%	5.4%
7	TOPICAL ANTI-INFLAMMATORY STEROIDAL	1,204,545	0.8%	1.2%	747,865	3.1%	5.5%
8	LAXATIVES AND CATHARTICS	1,467,041	2.0%	1.3%	720,773	4.7%	5.1%
9	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	1,792,759	1.5%	1.7%	712,076	3.7%	5.2%
10	ANTICONVULSANTS	2,875,159	3.1%	2.7%	647,563	4.6%	4.7%
11	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS	1,317,647	1.2%	1.2%	605,999	4.4%	4.3%
12	PROTON-PUMP INHIBITORS	1,827,638	1.7%	1.7%	588,337	3.9%	4.2%
13	ANTIEMETIC/ANTIVERTIGO AGENTS	822,632	1.1%	0.8%	561,669	4.1%	3.9%
14	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	2,219,107	1.8%	2.1%	532,377	3.2%	3.9%
15	ANALGESIC/ANTIPYRETICS,NON-SALICYLATE	771,946	1.0%	0.7%	526,378	3.9%	3.7%
16	PLATELET AGGREGATION INHIBITORS	1,922,602	2.2%	1.8%	499,028	4.3%	3.5%
17	CEPHALOSPORIN ANTIBIOTICS - 1ST GENERATION	567,617	0.8%	0.5%	483,049	3.6%	3.4%
18	ANTIHISTAMINES - 1ST GENERATION	1,060,255	1.0%	1.0%	473,198	2.8%	3.4%
19	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	1,750,782	2.1%	1.6%	452,454	4.2%	3.2%
20	NASAL ANTI-INFLAMMATORY STEROIDS	960,928	0.6%	0.9%	441,194	1.7%	3.3%

Table 5. Top 20 Drugs in the Medi-Cal Population.

This table presents utilization of the top 20 drugs in the Medi-Cal program, by **total utilizing beneficiaries.** The current year is compared to the prior year in order to illustrate changes in utilization for these drugs. The prior year ranking of each drug is listed for reference.

Table 5: Top 20 Drugs by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population							
Rank	Last Year Rank	Drug Description	Current Year 2021 Total Paid Claims	% Change from *Prior Year*	Current Year 2021 Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries *Prior Year*
1	1	IBUPROFEN	2,150,014	-29.1%	1,370,869	9.7%	-6.4%
2	850	COVID-19 VACC, MRNA (PFIZER)/PF	1,421,006	> 100%	824,420	5.9%	> 100%
3	3	AMOXICILLIN	885,639	-31.7%	725,838	5.2%	-3.5%
4	2	ALBUTEROL SULFATE	1,783,972	-32.4%	713,103	5.1%	-4.4%
5	4	ATORVASTATIN CALCIUM	2,114,673	-20.7%	556,278	4.0%	-3.0%
6	7	ACETAMINOPHEN	780,338	-28.9%	533,780	3.8%	-2.5%
7	6	FLUTICASONE PROPIONATE	1,155,901	-31.8%	513,331	3.6%	-2.9%
8	10	CHOLECALCIFEROL (VITAMIN D3)	1,611,103	-8.1%	505,834	3.6%	-1.6%
9	5	LORATADINE	1,275,665	-33.6%	495,355	3.5%	-3.0%
10	11	CEPHALEXIN	560,483	-21.0%	478,285	3.4%	-1.5%
11	8	ASPIRIN	1,762,418	-25.8%	467,518	3.3%	-2.8%
12	9	METFORMIN HCL	1,750,782	-23.1%	452,454	3.2%	-2.6%
13	13	HYDROCODONE/ ACETAMINOPHEN	966,151	-26.9%	417,048	3.0%	-1.7%
14	12	OMEPRAZOLE	1,243,130	-24.9%	399,924	2.8%	-2.0%
15	2146	COVID-19 VACC, MRNA(MODERNA)/PF	650,864	> 100%	377,196	2.7%	> 100%
16	14	LISINOPRIL	1,363,305	-26.5%	346,724	2.5%	-2.1%
17	17	GABAPENTIN	1,312,407	-24.8%	346,178	2.5%	-1.8%
18	16	BLOOD SUGAR DIAGNOSTIC	1,160,967	-23.5%	338,011	2.4%	-1.8%
19	21	TRIAMCINOLONE ACETONIDE	526,139	-23.7%	331,434	2.4%	-1.2%
20	15	AZITHROMYCIN	384,321	-42.2%	320,220	2.3%	-2.3%

Table 6. Top 20 Drugs in the Medi-Cal Population, by Program.

This table presents utilization of the top 20 drug therapeutic categories in the Medi-Cal program, by **total utilizing beneficiaries stratified by Medi-Cal program.**

Table 6: Top 20 Drugs by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program							
		Current Year 2021					
		Total Paid Claims			Total Utilizing Beneficiaries		
Rank	Medi-Cal	Medi-Cal	% FFS	% MCP	Medi-Cal	% FFS	% MCP
1	IBUPROFEN	2,150,014	2.6%	2.0%	9.7%	9.8%	9.7%
2	COVID-19 VACC, MRNA (PFIZER)/PF	1,421,006	1.6%	1.3%	5.9%	4.8%	5.9%
3	AMOXICILLIN	885,639	1.0%	0.8%	5.2%	4.1%	5.2%
4	ALBUTEROL SULFATE	1,783,972	1.5%	1.7%	5.1%	3.7%	5.2%
5	ATORVASTATIN CALCIUM	2,114,673	1.9%	2.0%	4.0%	4.0%	4.0%
6	ACETAMINOPHEN	780,338	1.0%	0.7%	3.8%	3.9%	3.8%
7	FLUTICASONE PROPIONATE	1,155,901	0.8%	1.1%	3.6%	2.2%	3.8%
8	CHOLECALCIFEROL (VITAMIN D3)	1,611,103	0.1%	1.6%	3.6%	0.3%	3.9%
9	LORATADINE	1,275,665	1.4%	1.2%	3.5%	2.8%	3.6%
10	CEPHALEXIN	560,483	0.8%	0.5%	3.4%	3.5%	3.4%
11	ASPIRIN	1,762,418	2.1%	1.6%	3.3%	3.9%	3.3%
12	METFORMIN HCL	1,750,782	2.1%	1.6%	3.2%	4.2%	3.2%
13	HYDROCODONE/ ACETAMINOPHEN	966,151	0.9%	0.9%	3.0%	3.2%	2.9%
14	OMEPRAZOLE	1,243,130	0.9%	1.2%	2.8%	2.3%	2.9%
15	COVID-19 VACC, MRNA (MODERNA)/PF	650,864	0.9%	0.6%	2.7%	2.6%	2.7%
16	LISINOPRIL	1,363,305	1.5%	1.3%	2.5%	3.0%	2.4%
17	GABAPENTIN	1,312,407	1.2%	1.2%	2.5%	2.3%	2.5%
18	BLOOD SUGAR DIAGNOSTIC	1,160,967	0.0%	1.2%	2.4%	0.1%	2.6%
19	TRIAMCINOLONE ACETONIDE	526,139	0.4%	0.5%	2.4%	1.4%	2.4%
20	AZITHROMYCIN	384,321	0.4%	0.4%	2.3%	1.8%	2.3%

QUARTERLY SUMMARY
MEDI-CAL PROGRAM DRUG USE REVIEW
REPORT PERIOD: 1st QUARTER 2022 (JANUARY – MARCH 2022)

Executive Summary

The DUR quarterly report provides information on both prospective and retrospective drug utilization for all claims processed by the Medi-Cal Rx program. For this quarterly report, the prospective and retrospective data cover the first quarter of 2022 (2022 Q1). Data sources are indicated for each table provided, with data reports generated exclusively from Medi-Cal Rx claims data provided by Magellan Medicaid Administration (MMA).

Prospective DUR

As shown in **Table 1.1**, a total of 53,153,578 claims were submitted for processing during 2022 Q1, with 28% generating DUR messages or alerts upon submission. Claims without DUR messages or alerts were more likely to be rejected (92% of rejected claims had no DUR messages or alerts) and claims with DUR messages or alerts were more likely to be denied (47% of denied claims had DUR messages or alerts).

Table 1.2 provides more details on the frequency of DUR messages or alerts (average of 1.00 per claim). A summary for each of the 13 prospective DUR alerts is provided in **Tables 2.1-2.13**, with greater detail provided on the total number of alerts, the total and percentage of alerts with outcomes denied or paid, total paid claims, and the percentage of paid claims that had an alert.

Retrospective DUR

Medi-Cal Rx pharmacy utilization data in **Table 3** show increases in total eligible beneficiaries and total utilizing beneficiaries from both the prior quarter (2021 Q4) and the prior-year quarter (2021 Q1). Total paid claims in 2022 Q1 decreased from the prior quarter by only 223 paid claims (< 1%) and increased in comparison to the prior-year quarter by 13%. In 2022 Q1, approximately 31% of eligible Medi-Cal Rx beneficiaries had a paid claim through Medi-Cal Rx.

As shown in **Table 4**, there were across-the-board decreases in utilizing beneficiaries and paid claims processed by Medi-Cal Rx in comparison to both the prior quarter and the prior-year quarter for the 65 years of age and older group, most likely due to the high utilization in the prior-year quarter of initial COVID-19 vaccines, and in the prior quarter for COVID-19 booster shots.

A review of the top 20 drug therapeutic categories in Medi-Cal Rx (**Table 5**) by percentage of utilizing beneficiaries with a paid claim showed across-the-board decreases in average paid claims per day and total percentage of utilizing beneficiaries with a paid claim in comparison to both the prior quarter and prior-year quarter for VITAMIN D PREPARATIONS and PLATELET AGGREGATION INHIBITORS.

Similarly, **Table 6** showed across-the-board decreases during 2022 Q1 for ASPIRIN and CHOLECALCIFEROL (VITAMIN D3). In addition, **Table 6** shows COVID-19 ANTIGEN TEST (ranked 17th) in the top 20 drugs by percentage of utilizing beneficiaries for the first time.

Appendix A: Prospective and Retrospective DUR Tables

Tables 1.1-1.2. Summary of Prospective DUR Alert Transactions in Medi-Cal Rx.

Table 1.1 provides summary level data (by volume) on pharmacy claims processing and DUR alert activities for the reporting period.

Table 1.1: Overview of Claims Processed – 2022 Q1						
Category	**Without DUR Alerts/Messages**		**With DUR Alerts/Messages**		**Grand Total**	
Paid	20,757,862	39.1%	7,565,535	14.2%	28,323,397	53.3%
Denied	4,614,661	8.7%	4,056,045	7.6%	8,670,706	16.3%
Reversed	7,555,292	14.2%	2,956,939	5.6%	10,512,231	19.8%
Rejected	5,103,725	9.6%	437,688	0.8%	5,541,413	10.4%
Duplicate	75,351	0.1%	30,480	0.1%	105,831	0.2%
Total Processed	***38,106,891***	***71.7%***	***15,046,687***	***28.3%***	***53,153,578***	***100.0%***

Data Sources: Magellan Medicaid Administration (MMA) Q1 Responses v2 Report

Table 1.2 provides a summary of the number of alerts and messages generated for each therapeutic problem type (sorted by alert frequency).

Table 1.2: Summary of Alert Transactions by Therapeutic Problem Type – 2022 Q1	
Therapeutic Problem Type	**Total Alerts/Messages**
Drug-Drug Interaction (DD)	6,393,460
Overuse Precaution (ER)	3,232,147
Drug-Disease (MC)	1,768,108
Underuse Precaution (LR)	1,536,548
Therapeutic Duplication (TD)	769,703
High Dose Alert (HD)	380,976
Ingredient Duplication (ID)	363,971
Low Dose Alert (LD)	273,627
Additive Toxicity (AT)	178,906
Drug-Age Precaution (PA)	167,143
High Cumulative MME (HC)	8,536
Drug-Pregnancy Alert (PG)	2,526
Drug-Allergy (DA)	1,136
All Alerts	**15,076,787**

Data Sources: Magellan Medicaid Administration (MMA) Q1 Responses v2 Report and Magellan Medicaid Administration (MMA) Q1 Received v1 Report

Tables 2.1-2.13. Prospective DUR Alert Transactions by Therapeutic Problem Type in Medi-Cal Rx.

Each of the following tables provides greater detail of each of the 13 DUR alerts with the top 10 drugs generating each respective alert. For each of the top 10 drugs, data are provided for the total number of alerts, the percentage of alerts with outcomes denied and paid, total claims submitted, total paid claims, and the percentage of paid claims that had an alert. **Tables are listed in order of DUR alert priority, which is determined by the DUR Board.**

Table 2.1: Top 10 Drugs by Therapeutic Problem Type – Drug-Allergy (DA) – 2022 Q1*

Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	OXYCODONE HCL	109	92	84.4%	16	14.7%	44,579	0.0%
2	HYDROCODONE/ ACETAMINOPHEN	92	56	60.9%	20	21.7%	310,866	0.0%
3	TRAMADOL HCL	77	56	72.7%	12	15.6%	82,265	0.0%
4	OXYCODONE HCL/ ACETAMINOPHEN	67	45	67.2%	9	13.4%	55,229	0.0%
5	GABAPENTIN	46	9	19.6%	17	37.0%	435,692	0.0%
6	MORPHINE SULFATE	32	30	93.8%	2	6.3%	18,762	0.0%
7	DULOXETINE HCL	28	4	14.3%	12	42.9%	107,549	0.0%
8	ATORVASTATIN CALCIUM	27	4	14.8%	5	18.5%	724,418	0.0%
9	HYDROXYZINE PAMOATE	25	20	80.0%	2	8.0%	51,800	0.0%
10	FLUOXETINE HCL	20	10	50.0%	6	30.0%	176,336	0.0%

*Data are available from pre-overridden alerts only for the DA alert.

Table 2.2: Top 10 Drugs by Therapeutic Problem Type – Drug-Pregnancy (PG) – 2022 Q1

Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	IBUPROFEN	263	70	26.6%	148	56.3%	774,789	0.0%
2	ATORVASTATIN CALCIUM	126	36	28.6%	73	57.9%	724,418	0.0%
3	LISINOPRIL	93	18	19.4%	64	68.8%	443,867	0.0%
4	ASPIRIN	82	26	31.7%	43	52.4%	518,737	0.0%
5	ALBUTEROL SULFATE	58	19	32.8%	28	48.3%	707,483	0.0%
6	HYDROCORTISONE	51	5	9.8%	14	27.5%	132,545	0.0%
7	DICLOFENAC SODIUM	49	13	26.5%	24	49.0%	214,540	0.0%
8	METRONIDAZOLE	46	16	34.8%	21	45.7%	91,455	0.0%
9	LEVOTHYROXINE SODIUM	46	9	19.6%	26	56.5%	333,902	0.0%
10	NAPROXEN	41	11	26.8%	28	68.3%	147,873	0.0%

Table 2.3: Top 10 Drugs by Therapeutic Problem Type – Drug-Disease (MC) – 2022 Q1								
Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	IBUPROFEN	249,776	35,384	14.2%	156,159	62.5%	774,789	20.2%
2	METFORMIN HCL	232,625	36,455	15.7%	145,834	62.7%	588,426	24.8%
3	ATORVASTATIN CALCIUM	163,243	35,370	21.7%	97,736	59.9%	724,418	13.5%
4	DICLOFENAC SODIUM	63,841	9,162	14.4%	37,923	59.4%	214,540	17.7%
5	QUETIAPINE FUMARATE	59,545	25,874	43.5%	24,583	41.3%	158,205	15.5%
6	BUPROPION HCL	57,240	26,941	47.1%	22,105	38.6%	175,620	12.6%
7	HYDROCHLOROTHIAZIDE	48,794	13,161	27.0%	27,544	56.4%	199,236	13.8%
8	NAPROXEN	45,649	7,671	16.8%	27,627	60.5%	147,873	18.7%
9	METOPROLOL SUCCINATE	43,044	9,269	21.5%	23,864	55.4%	142,369	16.8%
10	PROPRANOLOL HCL	40,926	8,014	19.6%	22,497	55.0%	82,133	27.4%

Table 2.4: Top 10 Drugs by Therapeutic Problem Type – Drug-Drug Interaction (DD) – 2022 Q1								
Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	HYDROCODONE/ ACETAMINOPHEN	260,095	83,917	32.3%	126,889	48.8%	310,866	40.8%
2	IBUPROFEN	229,845	12,534	5.5%	168,449	73.3%	774,789	21.7%
3	TRAZODONE HCL	189,601	38,784	20.5%	118,878	62.7%	214,820	55.3%
4	GABAPENTIN	183,867	56,950	31.0%	100,623	54.7%	435,692	23.1%
5	BUPROPION HCL	179,385	37,813	21.1%	106,153	59.2%	175,620	60.4%
6	ASPIRIN	149,434	32,924	22.0%	87,828	58.8%	518,737	16.9%
7	SERTRALINE HCL	141,344	21,456	15.2%	91,996	65.1%	267,025	34.5%
8	ESCITALOPRAM OXALATE	120,721	19,820	16.4%	75,304	62.4%	185,187	40.7%
9	LISINOPRIL	114,005	6,350	5.6%	85,216	74.7%	443,867	19.2%
10	FLUOXETINE HCL	109,991	18,924	17.2%	70,299	63.9%	176,336	39.9%

Table 2.5: Top 10 Drugs by Therapeutic Problem Type – Therapeutic Duplication (TD) – 2022 Q1								
Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	TRAZODONE HCL	53,668	31,756	59.2%	17,684	33.0%	214,820	8.2%
2	BUPROPION HCL	49,028	30,572	62.4%	13,933	28.4%	175,620	7.9%
3	ALBUTEROL SULFATE	47,308	29,233	61.8%	12,057	25.5%	707,483	1.7%
4	SERTRALINE HCL	36,723	22,368	60.9%	10,936	29.8%	267,025	4.1%
5	QUETIAPINE FUMARATE	34,355	21,153	61.6%	10,656	31.0%	158,205	6.7%
6	FLUOXETINE HCL	30,164	18,770	62.2%	8,850	29.3%	176,336	5.0%
7	ESCITALOPRAM OXALATE	26,916	16,616	61.7%	7,711	28.6%	185,187	4.2%
8	DULOXETINE HCL	22,932	14,196	61.9%	6,736	29.4%	107,549	6.3%
9	OLANZAPINE	22,075	13,536	61.3%	6,853	31.0%	98,596	7.0%
10	VENLAFAXINE HCL	20,505	12,849	62.7%	5,734	28.0%	76,621	7.5%

*Data are available from pre-overridden alerts only for the TD alert beginning January 21, 2022.

Table 2.6: Top 10 Drugs by Therapeutic Problem Type – Overutilization (ER) – 2022 Q1								
Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	ATORVASTATIN CALCIUM	105,908	27,760	26.2%	44,091	41.6%	724,418	6.1%
2	METFORMIN HCL	92,549	24,753	26.7%	36,910	39.9%	588,426	6.3%
3	GABAPENTIN	71,848	28,081	39.1%	24,996	34.8%	435,692	5.7%
4	ALBUTEROL SULFATE	69,250	25,154	36.3%	25,017	36.1%	707,483	3.5%
5	LISINOPRIL	68,078	18,575	27.3%	27,986	41.1%	443,867	6.3%
6	AMLODIPINE BESYLATE	67,544	18,260	27.0%	27,980	41.4%	412,620	6.8%
7	ASPIRIN	65,165	22,767	34.9%	25,287	38.8%	518,737	4.9%
8	BLOOD SUGAR DIAGNOSTIC	62,284	17,985	28.9%	28,183	45.2%	405,618	6.9%
9	LEVOTHYROXINE SODIUM	56,003	17,158	30.6%	20,471	36.6%	333,902	6.1%
10	HYDROCODONE/ ACETAMINOPHEN	54,453	53,487	98.2%	0	0.0%	310,866	0.0%

Table 2.7: Top 10 Drugs by Therapeutic Problem Type – Underutilization (LR) – 2022 Q1								
Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	ATORVASTATIN CALCIUM	166,964	16,976	10.2%	114,518	68.6%	724,418	15.8%
2	GABAPENTIN	144,347	23,726	16.4%	92,068	63.8%	435,692	21.1%
3	AMLODIPINE BESYLATE	94,487	10,003	10.6%	65,076	68.9%	412,620	15.8%
4	LEVOTHYROXINE SODIUM	91,627	17,784	19.4%	54,761	59.8%	333,902	16.4%
5	SERTRALINE HCL	82,118	12,920	15.7%	50,587	61.6%	267,025	18.9%
6	BUPROPION HCL	55,974	11,271	20.1%	32,013	57.2%	175,620	18.2%
7	ESCITALOPRAM OXALATE	55,381	9,191	16.6%	33,112	59.8%	185,187	17.9%
8	FLUOXETINE HCL	54,586	9,334	17.1%	33,833	62.0%	176,336	19.2%
9	QUETIAPINE FUMARATE	40,926	7,411	18.1%	24,630	60.2%	158,205	15.6%
10	ARIPIPRAZOLE	38,442	7,164	18.6%	22,480	58.5%	125,603	17.9%

Table 2.8: Top 10 Drugs by Therapeutic Problem Type – Additive Toxicity (AT) – 2022 Q1*								
Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	GABAPENTIN	39,321	3,332	8.5%	30,185	76.8%	435,692	6.9%
2	BACLOFEN	11,044	621	5.6%	8,582	77.7%	109,446	7.8%
3	CYCLOBENZAPRINE HCL	10,458	642	6.1%	8,270	79.1%	142,584	5.8%
4	TIZANIDINE HCL	5,946	354	6.0%	4,582	77.1%	38,282	12.0%
5	METHOCARBAMOL	5,195	265	5.1%	4,049	77.9%	44,471	9.1%
6	PREGABALIN	3,936	202	5.1%	2,968	75.4%	35,862	8.3%
7	HYDROCODONE/ ACETAMINOPHEN	2,706	1,163	43.0%	1,081	39.9%	310,866	0.3%
8	LORAZEPAM	1,633	457	28.0%	913	55.9%	81,384	1.1%
9	OXYCODONE HCL/ ACETAMINOPHEN	1,415	604	42.7%	472	33.4%	55,229	0.9%
10	TRAZODONE HCL	1,375	134	9.7%	1,067	77.6%	214,820	0.5%

*Outcome data are available from pre-overridden alerts only for the AT alert.

Table 2.9: Top 10 Drugs by Therapeutic Problem Type – Ingredient Duplication (ID) – 2022 Q1								
Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	ALBUTEROL SULFATE	45,036	26,919	59.8%	12,149	27.0%	707,483	1.7%
2	QUETIAPINE FUMARATE	20,356	12,910	63.4%	5,993	29.4%	158,205	3.8%
3	LEVOTHYROXINE SODIUM	17,311	11,011	63.6%	4,388	25.3%	333,902	1.3%
4	BUPROPION HCL	16,132	10,452	64.8%	4,094	25.4%	175,620	2.3%
5	FLUOXETINE HCL	14,780	9,466	64.0%	4,038	27.3%	176,336	2.3%
6	GABAPENTIN	14,843	9,436	63.6%	4,060	27.4%	435,692	0.9%
7	SERTRALINE HCL	13,578	8,692	64.0%	3,554	26.2%	267,025	1.3%
8	VENLAFAXINE HCL	11,090	7,037	63.5%	3,039	27.4%	76,621	4.0%
9	OLANZAPINE	11,267	7,046	62.5%	3,348	29.7%	98,596	3.4%
10	METFORMIN HCL	10,943	7,239	66.2%	2,343	21.4%	588,426	0.4%

*Data are available from pre-overridden alerts only for the ID alert beginning January 21, 2022.

Table 2.10: Top 10 Drugs by Therapeutic Problem Type – Drug-Age (PA) – 2022 Q1								
Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	ATORVASTATIN CALCIUM	95,451	18,992	19.9%	54,761	57.4%	724,418	7.6%
2	AMITRIPTYLINE HCL	23,868	6,926	29.0%	11,354	47.6%	55,315	20.5%
3	SIMVASTATIN	18,158	4,005	22.1%	10,076	55.5%	118,821	8.5%
4	DULOXETINE HCL	10,002	4,157	41.6%	3,770	37.7%	107,549	3.5%
5	PRAVASTATIN SODIUM	6,642	1,245	18.7%	3,773	56.8%	46,719	8.1%
6	DOXEPIN HCL	4,875	1,167	23.9%	2,251	46.2%	11,723	19.2%
7	CODEINE PHOSPHATE/ GUAIFENESIN	3,386	266	7.9%	2,342	69.2%	16,106	14.5%
8	LOVASTATIN	2,422	438	18.1%	1,278	52.8%	15,062	8.5%
9	CLOZAPINE	659	354	53.7%	209	31.7%	23,248	0.9%
10	VORTIOXETINE HYDROBROMIDE	487	161	33.1%	132	27.1%	7,262	1.8%

Table 2.11: Top 10 Drugs by Therapeutic Problem Type – High Dose (HD) – 2022 Q1								
Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	ACETAMINOPHEN	37,022	14,508	39.2%	13,551	36.6%	351,147	3.9%
2	IBUPROFEN	30,434	7,414	24.4%	14,622	48.0%	774,789	1.9%
3	HYDROCODONE/ ACETAMINOPHEN	23,344	14,402	61.7%	4,867	20.8%	310,866	1.6%
4	ESCITALOPRAM OXALATE	22,023	5,962	27.1%	11,236	51.0%	185,187	6.1%
5	PROMETHAZINE/ DEXTROMETHORPHAN	21,397	7,587	35.5%	9,198	43.0%	154,188	6.0%
6	OLANZAPINE	20,987	5,631	26.8%	11,352	54.1%	98,596	11.5%
7	ALBUTEROL SULFATE	15,006	3,191	21.3%	3,578	23.8%	707,483	0.5%
8	ZOLPIDEM TARTRATE	13,944	2,803	20.1%	7,316	52.5%	49,832	14.7%
9	CIPROFLOXACIN HCL/ DEXAMETH	11,065	903	8.2%	2,610	23.6%	6,588	39.6%
10	IPRATROPIUM BROMIDE	10,645	3,998	37.6%	4,016	37.7%	19,847	20.2%

Table 2.12: Top 10 Drugs by Therapeutic Problem Type – Low Dose (LD) – 2022 Q1								
Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	ATORVASTATIN CALCIUM	20,983	4,981	23.7%	11,602	55.3%	724,418	1.6%
2	DULOXETINE HCL	18,376	4,795	26.1%	9,498	51.7%	107,549	8.8%
3	DIVALPROEX SODIUM	15,831	4,000	25.3%	8,618	54.4%	93,908	9.2%
4	BUPROPION HCL	15,226	4,261	28.0%	7,941	52.2%	175,620	4.5%
5	LITHIUM CARBONATE	14,042	4,307	30.7%	6,965	49.6%	34,341	20.3%
6	NITROGLYCERIN	7,711	1,622	21.0%	4,262	55.3%	18,780	22.7%
7	ACYCLOVIR	5,945	1,648	27.7%	3,087	51.9%	52,596	5.9%
8	VENLAFAXINE HCL	5,909	3,303	55.9%	1,718	29.1%	76,621	2.2%
9	ALBUTEROL SULFATE	5,809	1,409	24.3%	1,830	31.5%	707,483	0.3%
10	METRONIDAZOLE	5,591	1,318	23.6%	2,337	41.8%	91,455	2.6%

Table 2.13: Top 10 Drugs by Therapeutic Problem Type – High Cumulative MME (HC) – 2022 Q1								
Rank	Drug	Total Claims with Alerts	Outcome Denied		Outcome Paid		Total Paid Claims	% Paid Claims with Alerts
			Total	%	Total	%		
1	OXYCODONE HCL	2,391	1,448	60.6%	714	29.9%	44,579	1.6%
2	HYDROCODONE/ ACETAMINOPHEN	1,829	1,435	78.5%	282	15.4%	310,866	0.1%
3	MORPHINE SULFATE	1,378	629	45.6%	564	40.9%	18,782	3.0%
4	OXYCODONE HCL/ ACETAMINOPHEN	992	702	70.8%	206	20.8%	55,229	0.4%
5	METHADONE HCL	580	292	50.3%	225	38.8%	5,143	4.4%
6	HYDROMORPHONE HCL	536	323	60.3%	159	29.7%	6,827	2.3%
7	FENTANYL	427	229	53.6%	151	35.4%	2,598	5.8%
8	TRAMADOL HCL	232	188	81.0%	30	12.9%	82,265	0.0%
9	ACETAMINOPHEN WITH CODEINE	49	34	69.4%	11	22.4%	47,285	0.0%
10	TAPENTADOL HCL	43	17	39.5%	22	51.2%	467	4.7%

*Data are extracted from pre-overridden alerts for the HC alert.

Data Sources: Magellan Medicaid Administration (MMA) Q1 Responses v2 Report and Magellan Medicaid Administration (MMA) Q1 Received v1 Report

Table 3. Summary of Medi-Cal Rx Pharmacy Utilization.

This table shows pharmacy utilization in Medi-Cal Rx, including the percent change from the prior quarter and prior-year quarter.

Table 3: Medi-Cal Rx Pharmacy Utilization Measures					
Category	Current Quarter 2022 Q1	Prior Quarter 2021 Q4	Prior-Year Quarter 2021 Q1	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*
Total Eligible Beneficiaries	15,441,176	15,281,704	14,657,642	**1.0%**	**5.3%**
Total Utilizing Beneficiaries	4,822,082	4,769,942	3,947,010	**1.1%**	**22.2%**
Total Paid Rx Claims	27,355,057	27,355,280	24,133,890	**0.0%**	**13.3%**
Average Paid Rx Claims per Day	303,945	297,340	268,154	**2.2%**	**13.3%**
Average Paid Rx Claims per Eligible Beneficiary	1.77	1.79	1.65	**-1.0%**	**7.6%**
Average Paid Rx Claims per Utilizing Beneficiary	5.67	5.73	6.11	**-1.1%**	**-7.2%**

Data Source: Magellan Medicaid Administration (MMA) First Rx Systems – Claims Processed Reports

Table 4. Medi-Cal Rx Pharmacy Utilization by Age Group.

This table presents pharmacy utilization data in Medi-Cal Rx, broken out by age group, including the percent change from the prior quarter and prior-year quarter.

Table 4: Medi-Cal Rx Pharmacy Utilization by Age Group						
Age Group (years)	Current Quarter 2022 Q1 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*
0 – 12	2,028,738	**1.3%**	**77.3%**	739,342	**3.6%**	**71.7%**
13 – 18	1,500,918	**8.6%**	**44.5%**	460,462	**8.2%**	**55.0%**
19 – 39	6,499,673	**5.8%**	**19.3%**	1,462,417	**1.4%**	**18.8%**
40 – 64	14,147,874	**0.5%**	**10.8%**	1,659,346	**0.7%**	**12.8%**
65+	3,177,849	**-15.2%**	**-14.8%**	500,515	**-7.3%**	**-3.2%**
Total*	27,355,052	**0.0%**	**13.4%**	4,822,082	**1.1%**	**22.2%**

Data Source: Magellan Medicaid Administration (MMA) Pharmacy Utilization by Age Reports

Table 5. Top 20 Drug Therapeutic Categories in Medi-Cal Rx.

This table presents utilization of the top 20 drug therapeutic categories in Medi-Cal Rx, by **total utilizing beneficiaries.** The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization and reimbursement dollars paid to pharmacies for these top utilized drugs. The prior-year quarter ranking of the drug therapeutic category is listed for reference.

Table 5: Top 20 Drug Therapeutic Categories by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population

Rank	Last Year Rank	Drug Therapeutic Category Description	Current Quarter 2022 Q1 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries from *Prior Quarter*	% Change Total Utilizing Beneficiaries *Prior-Year Quarter*
1	1	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	1,084,211	**0.9%**	**14.6%**	794,104	16.5%	**1.1%**	**18.2%**
2	19	COVID-19 VACCINES	790,306	**-3.1%**	**> 100%**	690,183	14.3%	**-0.4%**	**> 100%**
3	2	ANTIHYPERLIPIDEMIC-HMGCOA REDUCTASE INHIB(STATINS)	971,892	**-4.3%**	**8.2%**	565,262	11.7%	**-2.5%**	**9.8%**
4	4	ANTIHISTAMINES - 2ND GENERATION	727,536	**5.2%**	**19.7%**	469,185	9.7%	**10.1%**	**26.4%**
5	6	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	711,457	**4.1%**	**23.9%**	433,695	9.0%	**2.3%**	**27.8%**
6	10	PENICILLIN ANTIBIOTICS	489,754	**-3.4%**	**36.1%**	433,428	9.0%	**-4.2%**	**36.0%**
7	3	VITAMIN D PREPARATIONS	721,972	**-12.0%**	**-6.0%**	425,457	8.8%	**-5.7%**	**-1.2%**
8	5	ANTICONVULSANTS	965,673	**0.8%**	**5.5%**	382,702	7.9%	**-0.1%**	**4.7%**
9	7	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	757,926	**1.6%**	**9.0%**	357,861	7.4%	**0.8%**	**7.4%**
10	11	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	589,770	**-2.5%**	**7.4%**	345,842	7.2%	**-0.3%**	**9.5%**
11	8	PROTON-PUMP INHIBITORS	592,020	**-0.4%**	**2.0%**	340,557	7.1%	**0.9%**	**4.8%**
12	9	PLATELET AGGREGATION INHIBITORS	579,440	**-5.5%**	**-4.3%**	316,121	6.6%	**-1.8%**	**-1.2%**
13	12	ANTIHYPERTENSIVES, ACE INHIBITORS	545,595	**-3.9%**	**0.5%**	313,571	6.5%	**-1.6%**	**2.2%**
14	22	ANALGESIC/ANTIPYRETICS, NON-SALICYLATE	351,767	**19.1%**	**49.2%**	290,716	6.0%	**17.7%**	**50.7%**
15	14	TOPICAL ANTI-INFLAMMATORY STEROIDAL	399,779	**7.4%**	**9.8%**	279,547	5.8%	**7.4%**	**9.5%**
16	13	LAXATIVES AND CATHARTICS	481,914	**-1.8%**	**5.2%**	276,517	5.7%	**0.0%**	**7.0%**
17	15	CALCIUM CHANNEL BLOCKING AGENTS	475,334	**-3.4%**	**7.3%**	268,546	5.6%	**-2.2%**	**8.1%**
18	20	NASAL ANTI-INFLAMMATORY STEROIDS	357,843	**11.0%**	**22.4%**	255,572	5.3%	**14.2%**	**28.5%**
19	17	BLOOD SUGAR DIAGNOSTICS	406,359	**-5.4%**	**-1.2%**	239,053	5.0%	**-4.1%**	**0.7%**
20	28	ANTIEMETIC/ANTIVERTIGO AGENTS	316,475	**12.0%**	**38.7%**	237,269	4.9%	**12.7%**	**45.3%**

Data Source: Magellan Medicaid Administration (MMA) Top 20 Therapeutic Class Reports

Table 6. Top 20 Drugs in Medi-Cal Rx.

This table presents the utilization of the top 20 drugs in Medi-Cal Rx, by **total utilizing beneficiaries.** The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization for these drugs. The prior-year quarter ranking of each drug is listed for reference.

Table 6: Top 20 Drugs by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population

Rank	Last Year Rank	Drug Description	Current Quarter 2022 Q1 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries from *Prior Quarter*	% Change Utilizing Total Utilizing Beneficiaries *Prior-Year Quarter*
1	1	IBUPROFEN	775,471	**2.6%**	**20.3%**	620,185	12.9%	**2.3%**	**23.2%**
2	3	ALBUTEROL SULFATE	708,861	**3.6%**	**24.2%**	434,310	9.0%	**1.9%**	**28.4%**
3	2	ATORVASTATIN CALCIUM	726,229	**-4.0%**	**10.8%**	426,193	8.8%	**-1.8%**	**12.1%**
4	4	METFORMIN HCL	589,770	**-2.5%**	**7.4%**	345,842	7.2%	**-0.3%**	**9.5%**
5	10	AMOXICILLIN	350,417	**-4.9%**	**37.2%**	317,521	6.6%	**-5.8%**	**37.5%**
6	N/A	COVID-19 VAC, TRIS(PFIZER)/PF	370,049	**> 100%**	**N/A**	305,957	6.3%	**> 100%**	**N/A**
7	5	ASPIRIN	520,288	**-6.0%**	**-5.9%**	300,927	6.2%	**-2.2%**	**-2.3%**
8	11	FLUTICASONE PROPIONATE	435,619	**10.4%**	**22.7%**	294,039	6.1%	**12.8%**	**28.1%**
9	15	ACETAMINOPHEN	351,767	**19.1%**	**49.2%**	290,716	6.0%	**17.7%**	**50.7%**
10	9	LORATADINE	427,535	**2.4%**	**10.9%**	276,526	5.7%	**7.3%**	**16.9%**
11	6	CHOLECALCIFEROL (VITAMIN D3)	421,578	**-20.3%**	**-13.0%**	262,679	5.4%	**-13.3%**	**-7.2%**
12	7	LISINOPRIL	444,769	**-4.0%**	**2.1%**	255,704	5.3%	**-1.8%**	**4.0%**
13	8	BLOOD SUGAR DIAGNOSTIC	406,359	**-5.4%**	**-1.2%**	239,053	5.0%	**-4.1%**	**0.8%**
14	13	AMLODIPINE BESYLATE	413,668	**-3.3%**	**7.6%**	236,975	4.9%	**-1.9%**	**8.6%**
15	12	OMEPRAZOLE	391,573	**-0.9%**	**-2.0%**	232,865	4.8%	**1.0%**	**1.6%**
16	14	GABAPENTIN	437,028	**0.1%**	**4.4%**	220,147	4.6%	**-0.7%**	**4.3%**
17	N/A	COVID-19 ANTIGEN TEST	262,091	**N/A**	**N/A**	199,882	4.1%	**N/A**	**N/A**
18	29	COVID-19 VACC, MRNA (PFIZER)/PF	209,863	**-57.0%**	**42.7%**	199,067	4.1%	**-51.4%**	**79.7%**
19	40	COVID-19 VACC,MRNA (MODERNA)/PF	202,827	**-8.0%**	**97.8%**	190,792	4.0%	**-7.7%**	**125.2%**
20	24	CETIRIZINE HCL	272,179	**8.7%**	**34.9%**	186,546	3.9%	**14.4%**	**43.8%**

Data Source: Magellan Medicaid Administration (MMA) Top 20 Drug Reports

MEDI-CAL DRUG USE REVIEW (DUR) PROGRAM
QUARTERLY EVALUATION REPORT – 1st Quarter 2022

The purpose of the educational intervention component of DUR is to improve the quality and cost-effectiveness of prescribing and dispensing practices for Medi-Cal beneficiaries. Educational interventions include ongoing dissemination of clinically important information through the Medi-Cal provider bulletin process.

DUR educational articles are published in provider bulletins and posted on the Educational Articles page on the DUR website. Two years after publication, each article is reviewed again in a systematic way in order to evaluate any change over time. These evaluations are conducted quarterly and use the following template:

- Background
- Purpose
- Data Criteria and Findings
- Analysis
- Limitations
- Research/Policy Recommendations
- Clinical Recommendations
- Board Recommendations

Many factors may influence the prescribing and dispensing practices of Medi-Cal providers, making it difficult to accurately measure the full impact of the educational articles. Such factors may include, but are not limited to, the following:

- Changes and updates to treatment guidelines and recommendations
- Beneficiary expectations and requests and healthcare habits and behavior
- Direct-to-consumer advertising
- Provider training and experience
- Anecdotal experience
- Provider resistance
- Extent of readership
- Exposure to multiple sources of continuing education

The purpose of DUR educational articles is to apprise Medi-Cal providers and pharmacies of current treatment guidelines and recommendations on drugs, disease states, and medical conditions. These articles contain valuable information that is effective when used as a part of an overall campaign to disseminate timely and needed information to providers and pharmacies.

The following recommendations may help to improve accessibility, reach, and interest of educational articles to the Medi-Cal provider and pharmacy community:

- Continue to distribute articles through normal publication channels, but also send articles separate and independent from the bulletin, in order to increase visibility.
- Distribute article links to medical and pharmaceutical organizations/associations for distribution to their members or publications in journals and/or bulletins.
- Encourage prescribers and pharmacists to sign up for distribution of DUR articles via the Medi-Cal Subscription Service (MCSS).
- Facilitate continuing medical education (CME) and/or continuing education (CE) opportunities to prescribers and pharmacists related to article content.
- Incorporate case studies into articles.
- Package articles with other collateral materials for distribution through various media channels such as posters, postcard mailings and flyers that highlight the recommendations of each article.
- Disseminate shorter educational alerts that highlight relevant and important topics that can be published with greater frequency.
- When appropriate, disseminate lay versions of articles to beneficiaries to promote physician uptake and set beneficiary expectations.
- Continue to support the direct link between articles and retrospective DUR educational outreach to prescribers and pharmacists.
- Increase understanding of prospective DUR alert methodology, by using articles to focus on drug therapy problems that are frequently overridden at the pharmacy level.
- Include patient-specific profiles for educational outreach where the primary objective is an improvement in the quality of care.
- Use provider-specific profiles for educational outreach where the primary objective is an improvement in the quality of prescribing.
- Use pharmacy-specific profiles for educational outreach where the primary objective is an improvement in the quality of dispensing.

This quarterly evaluation report provides a detailed evaluation of the following DUR educational article that was published between January 2020 and March 2020:

- Drug Safety Communication: Mental Health Side Effects from Montelukast – March 2020

Evaluation of Educational Articles

Drug Safety Communication: Mental Health Side Effects from Montelukast – published March 2020

- **Background:** Montelukast is a leukotriene receptor antagonist (LRTA) approved for asthma and allergies. On March 4, 2020, the U.S. Food and Drug Administration (FDA) announced the requirement for a Boxed Warning to be added to the montelukast prescribing information. The Boxed Warning describes serious mental health side effects with montelukast and recommends that montelukast be reserved to treat allergic rhinitis only in patients who cannot tolerate or are not being treated effectively with other allergy medications.

- **Purpose:** The purpose of this evaluation is to review the FDA safety communications on montelukast since the publication of the original article and to describe any relevant updates.

- **Data Criteria and Findings:** Since the publication of this educational article, there have been no additional alerts related to FDA safety concerns for montelukast.

  An outreach letter to providers regarding montelukast was sent by the DUR program on April 24, 2020. The letter was sent to the top 223 prescribers of montelukast (by the total number of Medi-Cal Fee-for-Service (FFS) beneficiaries prescribed montelukast between January 1, 2020, and April 15, 2020). Each of the 223 prescribers that was sent the letter had prescribed montelukast to at least 5 beneficiaries in 2020, and while these prescribers represented only 3% of all montelukast prescribers, they prescribed montelukast to 26% of all beneficiaries identified with a paid claim for montelukast during this period. Each prescriber was sent a letter that included the Medi-Cal DUR alert and provider survey. The objective of the mailing was to inform health care providers of the possible risks associated with use of montelukast.

  The primary outcome was the total number of paid claims for montelukast prescribed within 12 months of the mailing, which was 47.5% (n = 710) of continuously eligible patients (n = 1,495). The 223 prescribers had a 48.1% decrease in patients with a paid claim for montelukast during the same period in 2021 (January 1, 2021, through April 15, 2021).

  An analysis of the secondary outcome showed that 25.1% of continuously eligible patients with paid claims for montelukast had concomitant diagnosis codes indicating mental health side effects after 12 months, which was almost identical to the 25.2% reported among the continuously eligible patients at baseline. For this mailing, the final response rate within 90 days of mailing was

15% and the undeliverable rate for the letter was 2%.

- **Analysis:** Guideline recommendations for allergic rhinitis and asthma have been updated since the original article was published, to incorporate the FDA's warning for montelukast. The guideline on allergic and nonallergic rhinitis titled Rhinitis 2020: A practice parameter update, now recommends that clinicians 1) avoid LRTAs for treatment of nonallergic rhinitis and 2) reserve LRTAs for treatment of allergic rhinitis with inadequate response or intolerance to alternative therapies. In the case that montelukast is used, the guideline recommends providers to use a shared decision-making approach with the patient and weigh the risks and benefits of treatment. The 2021 update of the Global Strategy for Asthma Management and Prevention list LRTAs as an alternative option for asthma management and encourage providers to weigh the risks of montelukast due to the FDA's Boxed Warning.

- **Limitations:** None.

- **Research/Policy Recommendations:**
  1. Continue to monitor research and FDA communications regarding montelukast.
  2. Continue to monitor the use of montelukast in the Medi-Cal population.

- **Clinical Recommendations:**
  1. Health care providers should prescribe montelukast for allergic rhinitis only when patients have had an inadequate response or intolerance to alternative therapies.
  2. Counsel all patients receiving montelukast about the risk of mental health side effects and advise them to stop the medicine and contact a health care professional immediately if they develop any mental health side effects, including suicidal thoughts or actions.
  3. Health care professionals should be aware that some patients have reported neuropsychiatric events after discontinuation of montelukast.
  4. Discuss the possible option of other safe and effective allergy medicines with patients and parents or caregivers, including over-the-counter products or allergen immunotherapy.

- **Board Recommendations:**
  1. No recommendations at this time.