

BACKGROUND

- Treatment options for Crohn's disease (CD) have expanded substantially in recent decades.
- The June 2021 American Gastroenterological Association guideline for CD strongly recommended the use of biologic monotherapy over thiopurine monotherapy for induction of remission.
- However, access to biologics is often limited by utilization management practices in U.S. commercial insurance coverage decisions.
- Step therapy requires patients to try alternative treatments and demonstrate inadequate response or intolerance before accessing targeted therapies.

OBJECTIVE

- To assess biologic use in CD and its alignment with step therapy protocols imposed by commercial health plans.

METHODS

- Data Source: Virginia All-Payer Claims Database (APCD), administered by Virginia Health Information, linked with the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database
- Study Population: Adults aged 18–64 Years with newly diagnosed CD, 2018–2021

RESULTS

- Among patients with documented conventional therapy failure, 85.8% (121/141) had treatment patterns consistent with health plan step-therapy protocols.
- Among patients without documented conventional therapy failure, only 17.2% (67/390) had treatment patterns consistent with step-therapy protocols.

RESULTS

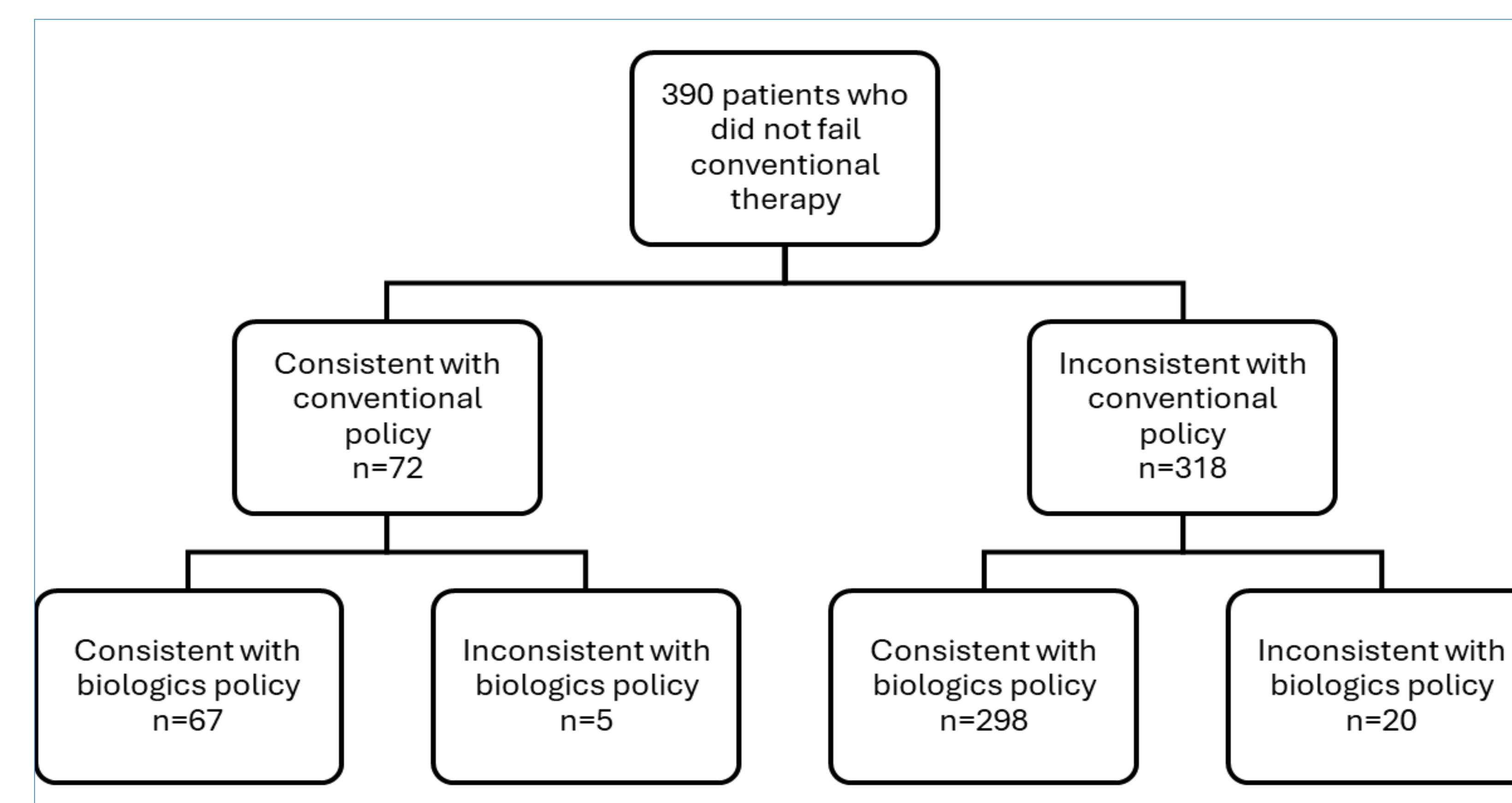
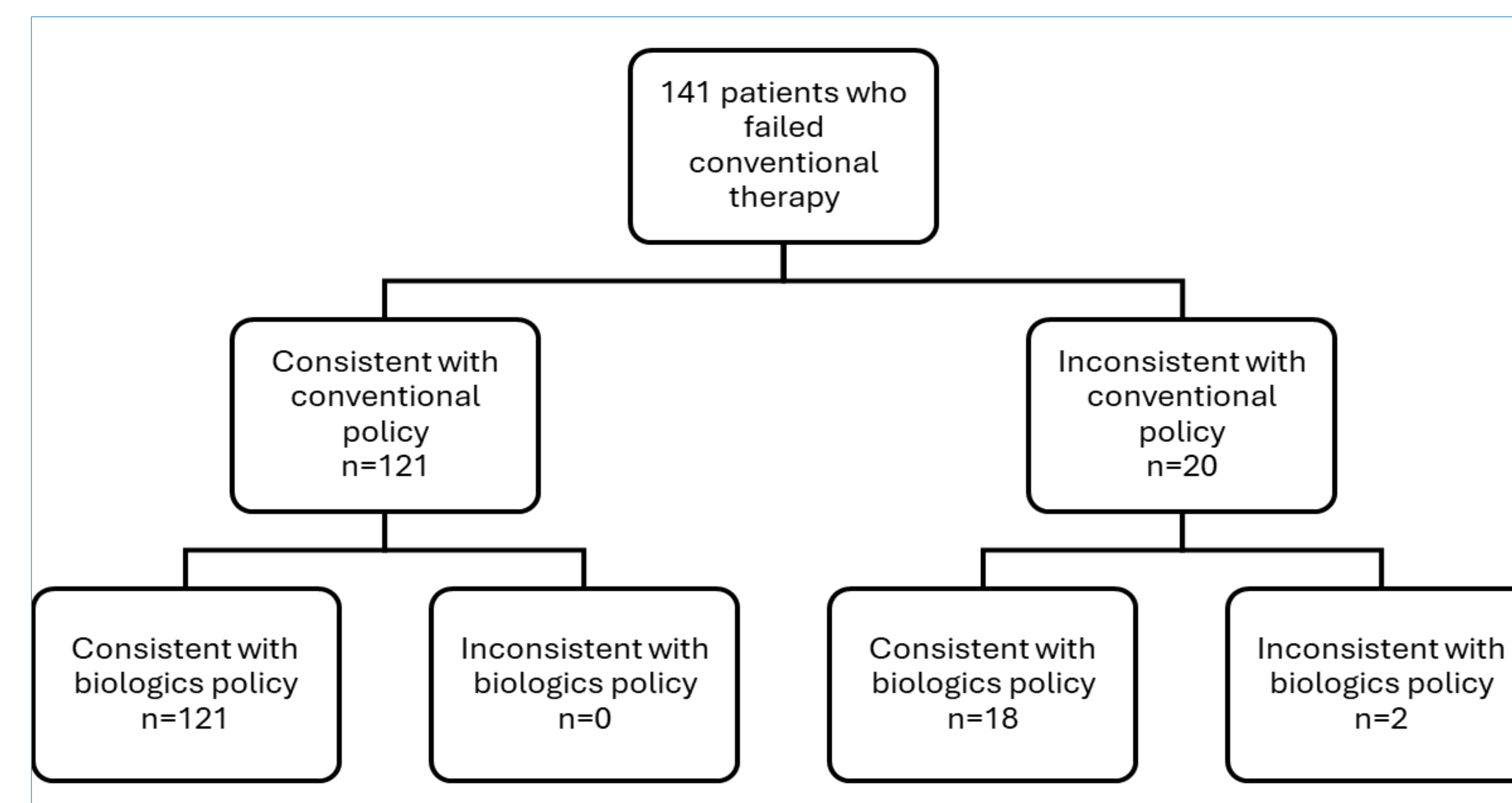
Table 1. Patients with newly diagnosed CD aged 18–64: APCD, 2018–2021

| Steps | Number of patients |
|--|--------------------|
| Step One: Patients meeting newly diagnosed CD criteria, 2017–2022 | 9,490 |
| Step Two: All patients meeting high likelihood of being a case | 7,646 |
| Step Three: Patients with CD, index date 2018–2021 | 2,137 |
| Step Four: Patients aged 0–64, index date between 2018 and 2021 | 1,948 |
| Step Five: Keep patients with only "paid" and "encounter" claims | 1,947 |
| Step Six: Patients aged 0–64 insurance coverage captured in the SPEC dataset | 1,378 |
| Step Seven: Patients with CD who had at least one claim of biologic therapy | 604 |

Table 2. Treatment pathway within one year after newly diagnosed CD aged 0–64: APCD, 2018–2021

| Treatment Pathway | Number of patients | Proportion of overall (N=1,378) | Proportion of patients received any biologic (N=604) |
|------------------------------|--------------------|---------------------------------|--|
| (1) Any biologic therapy | 604 | 43.83% | 100.00% |
| i. One biologic | 532 | 38.61% | 88.08% |
| ii. Two or more biologics | 72 | 5.22% | 11.92% |
| (2) Any conventional therapy | 724 | 52.54% | - |

Figure 1, 2. Alignment of utilization patterns of biologics with step therapy protocols among patients with and without conventional therapy failure



DISCUSSION

- Health plan coverage policies often impose step therapy restrictions on biologic use in CD.
- Although health plans typically require failure of conventional therapies, many patients access to biologics without documented conventional therapy failure.
- In contrast, the biologic agents used in practice generally align with those designated as preferred by health plans, indicating strong consistency between coverage policy and real-world biologic selection.

CONCLUSION

Discrepancies between real-world biologic utilization and coverage policies suggest that clinical discretion and physician judgment play an important role in treatment decisions, alongside health plan requirements.

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