

Current Formulary Based Cholesterol Management in the United States

Richard A. Brook, MS, MBA^{1,2} and Jim E. Smeeding, RPh, MBA^{1,3}

¹TPG-NPRT, Glastonbury, CT, US; ²The JeSTARx Group, Newfoundland, NJ, US; ³The JeSTARx Group, Dallas, TX, US



The TPG-National Payor Roundtable (TPG-NPRT) focuses on market access programs within the United States, is a subsidiary of The Pharmacy Group, and maintains a database of Chief Medical Officers and Chief Pharmacy Officers in the United States.



The JeSTARx Group provides evidence-based research and support to the healthcare industry.

BACKGROUND

- Cholesterol is managed by:
 - Initially by dietary and lifestyle changes
 - If those don't work, there are numerous drugs and therapies that are being used to manage cholesterol
- Cholesterol therapies:
 - Include several classes of agents working in different ways and with different targets
 - Are available branded and generic
 - Newer therapies have become available with different targets, higher prices and requiring clinician-administration
 - Managed by treating elevated triglycerides
- This contributes to patients paying different cost-shares for cholesterol management. Many of the agents to treat hypercholesterolemia have become generically available
- Pharmaceutical agents available in the United States differ from those available in other countries
- Work in conjunction with agents to manage elevated triglycerides and lipids

OBJECTIVES

- This study sought to survey Medical Directors and Pharmacy Directors of US payors representing: health plans, insurers, employer groups and Pharmacy Benefit Managers (PBMs)
- The survey focused on the:
 - Formulary status and tier for the different types of therapies used to manage cholesterol
 - Classes requiring mandatory generics and prior authorization
 - Current and anticipated future:
 - Policies regarding the use of co-pays for cholesterol agents
 - The newer Specialty Pharmacy offerings

METHODS

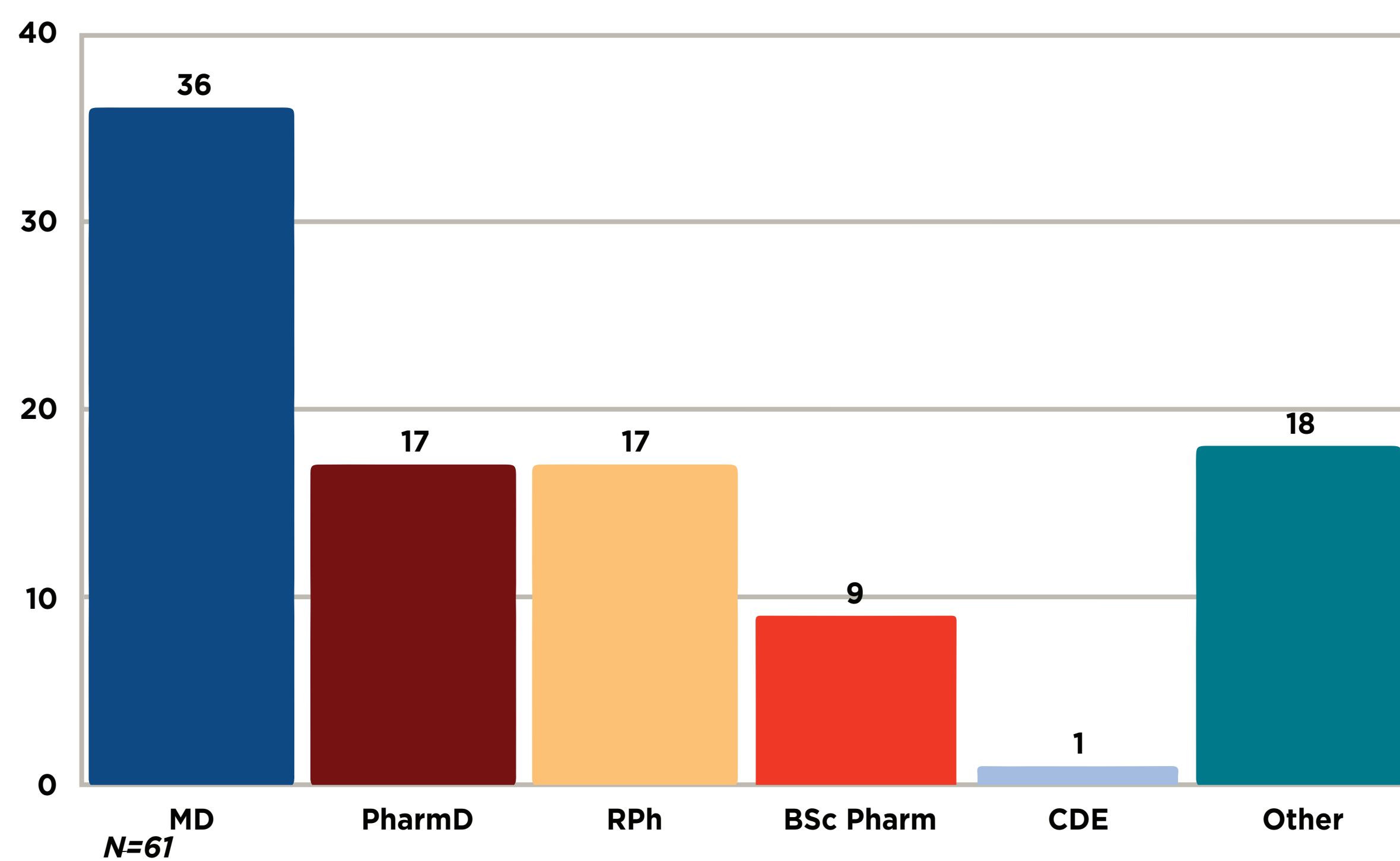
- Managed care Medical and Pharmacy Directors completed an online interactive survey
- An online, interactive survey was developed with 76 questions and included:
 - Yes / No questions
 - Lists for users to select single or multiple answers
 - Open-ended responses (i.e., what disease states most concern you?)
 - Invitations to participate were sent to Medical and Pharmacy Directors currently employed by US health plans and insurers from the TPG-NPRT database in December 2015
 - Material or financial incentives were not offered for completion of the survey
- Topics included:
 - Plan coverage:
 - Geographical coverage
 - Types of lives
 - Medication-based management of cholesterol:
 - Classes of drugs available and restricted
 - Therapies were ranked by the level of restriction



RESULTS

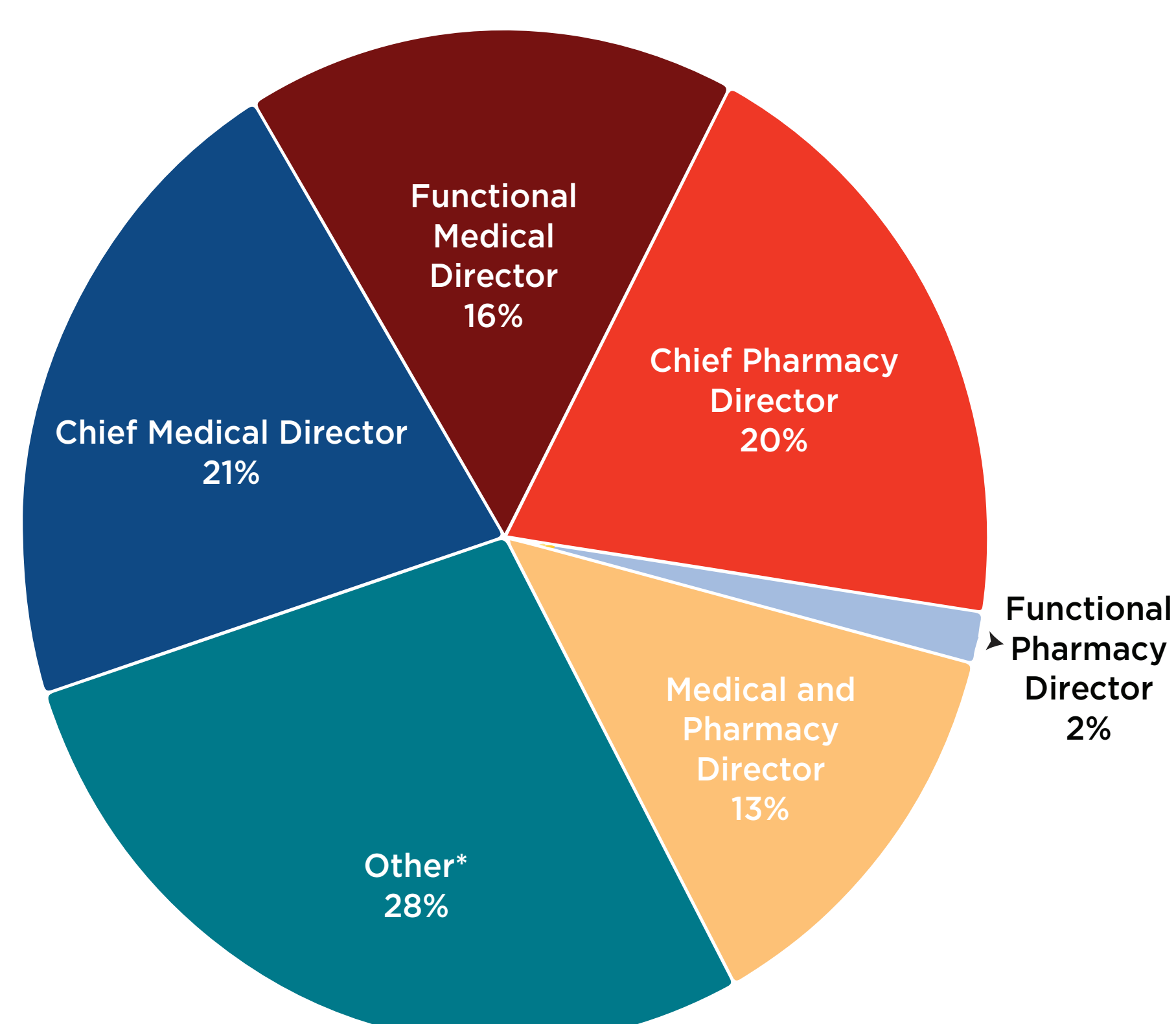
- The survey was completed by 61 persons—some questions were not answered by all respondents
- Many advisors reported multiple degrees (Figure 1), and the most common degree was MD (59.2%). 86% of the advisors were involved in formulary decisions

Figure 1: Respondent Degrees



- The respondents were mostly Chief Medical Directors and Chief Pharmacy Directors (Figure 2), functional Medical or Pharmacy Directors

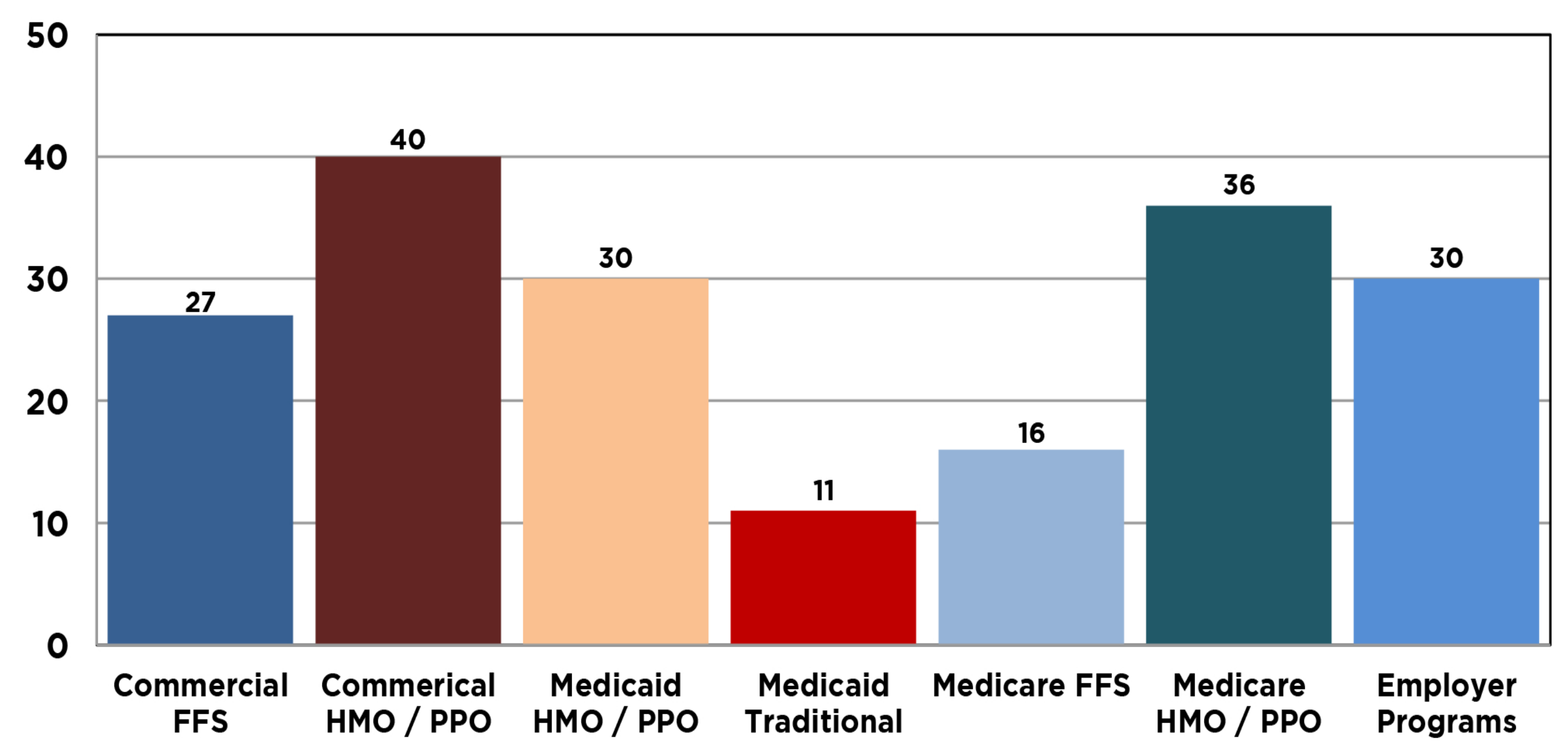
Figure 2: Respondent Titles



RESULTS CONTINUED

- Fifty-nine percent of respondents were MDs, with the remainder comprising mostly of pharmacists who largely worked for a health plan (62.3%).
- The health plans were 41.1% national, 30.4% regional, and 28.6% local
- Plans could cover multiple types of members (Figure 3)
- Therapies were ranked by the level of restriction (Figure 4)
 - The highest Prior Authorization rates were for: Proprotein Convertase Subtilisin/Kexin type 9 (PSC9s) inhibitors (*alirocumab* and *evolocumab*)=84.62%, *lomitapide*=71.1%
 - Classes with generic options were often first tier and included statins=47.2%, triglycerides=33.3%; fibrates=29.4%
 - Combination cholesterol agents=44.2% and cholesterol/cardiovascular combinations=43.1% and were mostly in tier 2
 - While over the counter (OTC) fish-oil products and supplements were generally unrestricted in Medicaid plans, not covered by Commercial or Medicare plans; the prescription therapy *icosapent* required Prior Authorization
 - The most common tier 2 products included *ezetimibe* (40.4%) followed by the bile-acid sequestrants (32.7%) of the time compared with fibrates

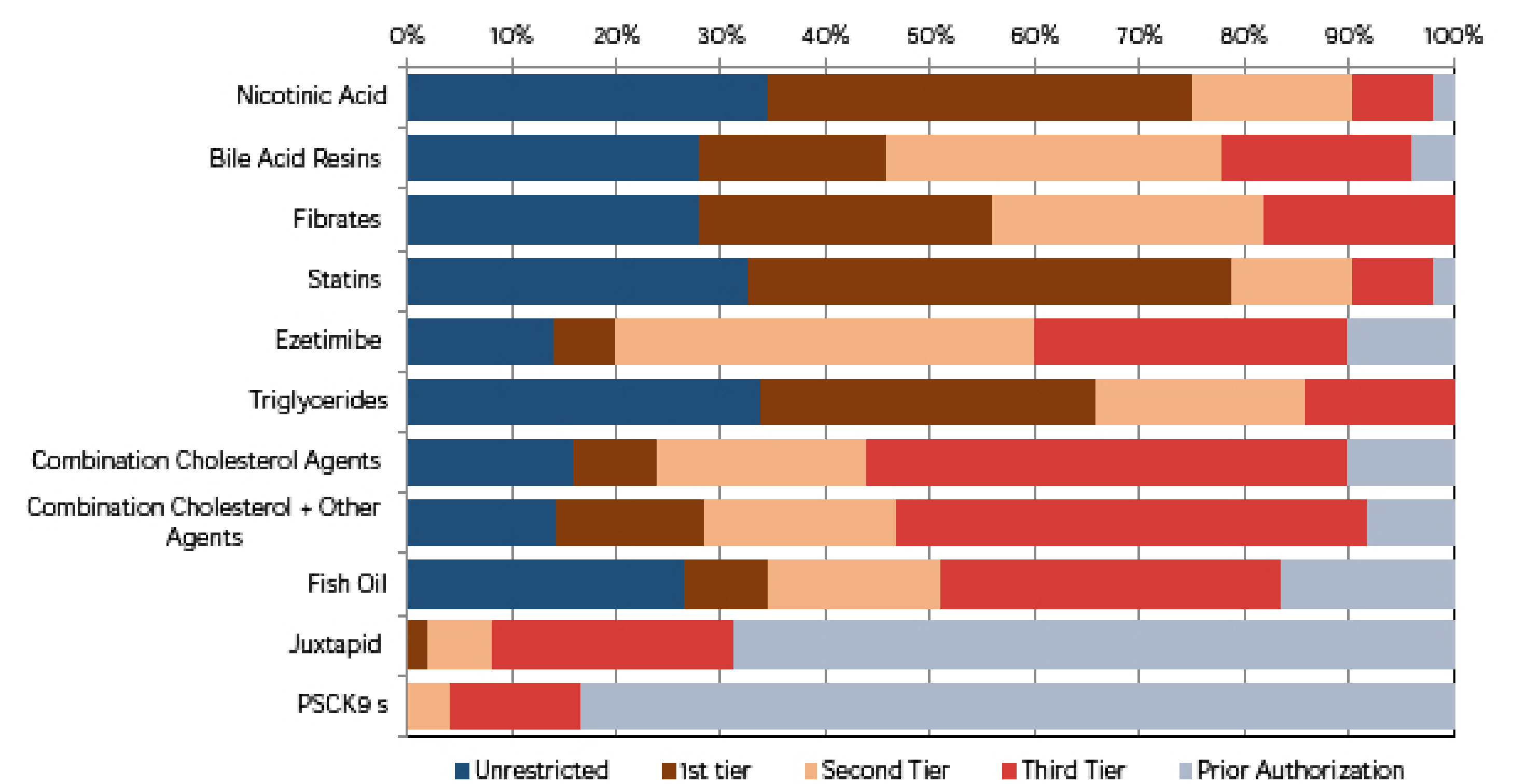
Figure 3: Plan Payor Coverage



N=61

FFS=Fee For Service; HMO=Health Maintenance Organizations; PPO=Preferred Provider Organization; Medicare=Care for the aged and special populations; Medicaid=Care for the poor

Figure 4: Plan Coverage for Cholesterol Therapies



CONCLUSIONS

- The environment for cholesterol management is undergoing a series of changes
- As new products enter the cholesterol management market, health plans will likely impose restrictions and plan designs on new classes favoring less expensive, generically available agents until real world effectiveness (RWE) data becomes available

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