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Addressing Drug Wastage: A $3 Billion Challenge

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In a study conducted by Bach et al., it was estimated that within the oncology drug class alone there was $3 Billion in potential wastage each year. To address this challenge, RJ Health examined drug wastage data (both industry and RJ Health Benchmark), its impact to overall drug spend, and several potential solutions.

What is Drug Wastage?

Drug wastage is defined as the unused portion of a drug package that is not administered to the patient. Many injectable drugs are packaged in either single or multi-dose vials. Multi-dose vials can be used for multiple patients and typically include some type of bacteriostatic agent (a biological or chemical agent that stops bacteria from reproducing) that allows the health care professional to use the required amount of drug and then keep whatever is left over for later use. Alternatively, a single-dose package can only be utilized once and then the unused portion is thrown away. Therefore, the drug that remains after the appropriate dose is removed is considered wastage and, under normal conditions, cannot be kept for use for another patient. Across drugs that are administered in the professional setting we have estimated that 62 percent of NDCs are currently formulated as single-dose (Figure 1), suggesting that NDCs susceptible to wastage *reflects a significant amount of drug spend*. When viewing these drugs as specialty and non-specialty, it can be observed that a greater number of specialty drugs (84%) are single-dose formulations compared with non-specialty (67%). Typically, specialty drugs are significantly higher priced than non-specialty, suggesting that this group would have the greatest impact on spend in regard to how wastage is billed and managed.

In addition, many of the highest cost therapeutic categories consist of many single-dose NDCs, raising the importance in proper wastage management (Figure 2).

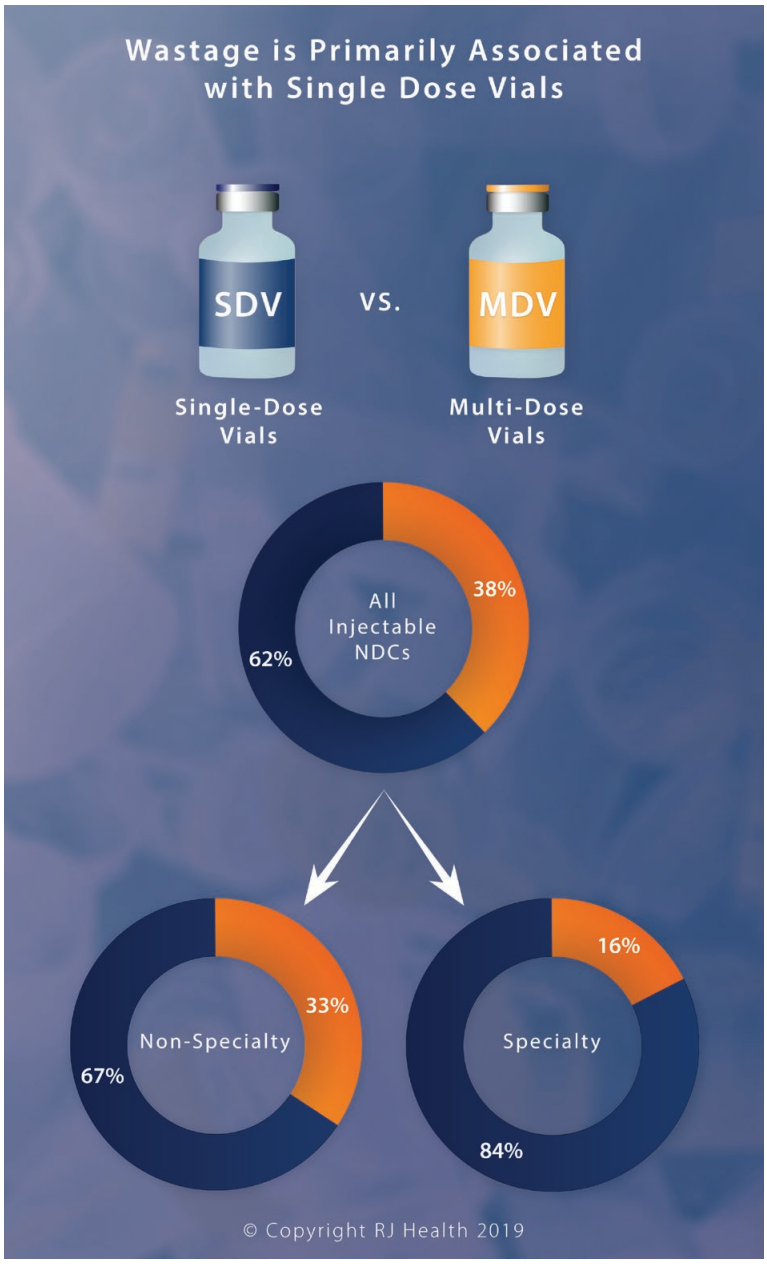

Figure 1: Percentage of drugs administered by health care professionals that are single versus multi-dose formulations and by Drug Type

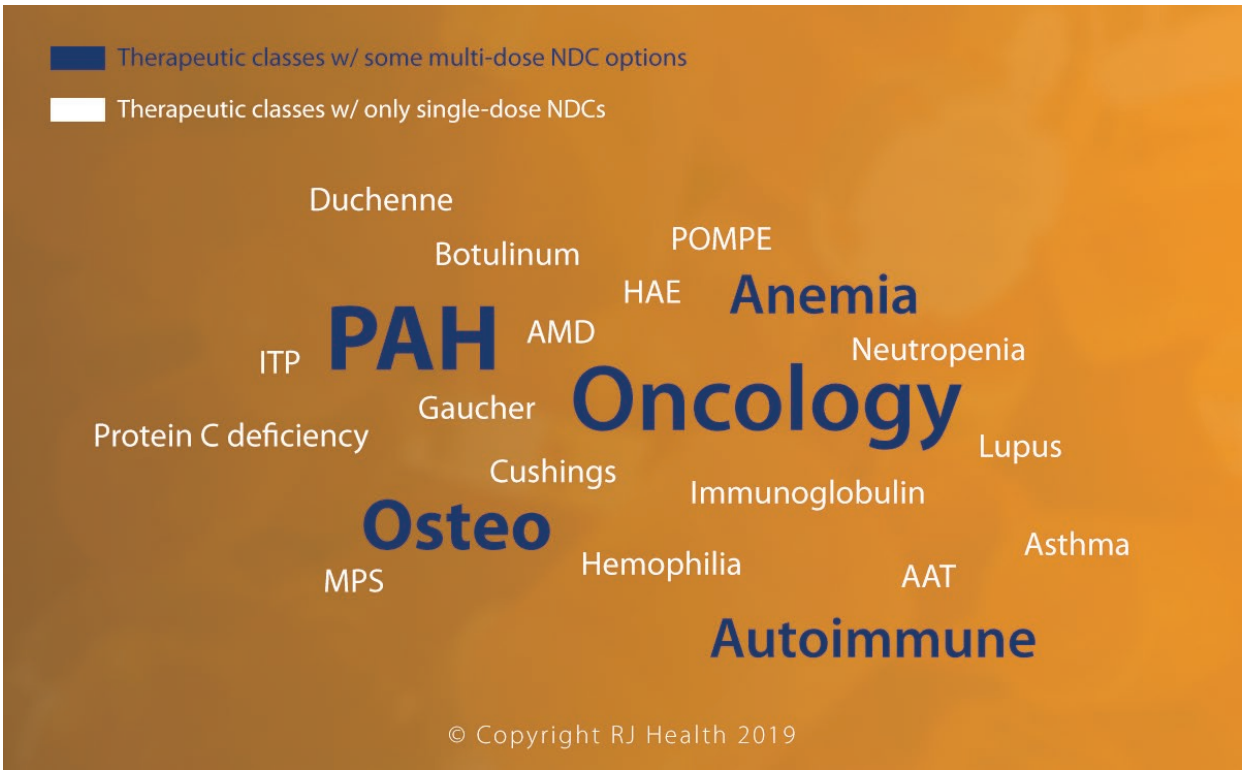

Figure 2: NDC formulation type for top cost therapeutic classes

How Does Drug Wastage Occur?

Although drug wastage can occur across many drugs, escalating drug pricing and greater focus on specialty drugs has raised wastage to a higher priority as an area to rein in health care costs. Much of this wastage can be attributed to the vial size and leftover drug in the single-dose vial after the dose is extracted. These expensive infused/injectable drugs are packaged in quantities larger than the amount needed, for which dosage is based on *a patient's weight or body size,* and that come in single-dose packages. An example, Abraxane® (paclitaxel protein-bound), which is a drug utilized for multiple cancer types has a 260 mg per m^2 dose for usage in metastatic breast cancer and is available in a 100mg vial. An average person who has a body surface area of 1.95m^2 (170 pounds and 70 inches) would require a dose of 507 mg, which results in 93 mg of waste at a cost of $1,281 using wholesale acquisition cost (WAC) (Figure 4).

	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER
1	N457894003001 UN3.5									
	08	08	18	08	08	18	11		J1745	
2	N457894003001 UN0.5									
	08	08	18	08	08	18	11		J1745	JW

Figure 3: Sample claim for Remicade J1745

Medicare and many health plans have incorporated wastage policies into their billing requirements. To ensure appropriate reimbursement, providers are required to submit two claim lines for the administered drug

within the same claim. One claim line reflects the dosage administered to the patient and the second is for the wastage amount (Figure 3). To ensure that the claim line for wastage is properly documented, a claim line modifier (JW) is required. The JW modifier is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier that is commonly used for Medicare Part B drug claims to report the amount of drug or biological that is discarded and eligible for payment under the discarded Drug/Drug Wastage policy. This also assists CMS and Health plans in tracking wasted drug costs.

Figure 4: Wastage of average Albraxane (pacitaxel protein-bound) dose

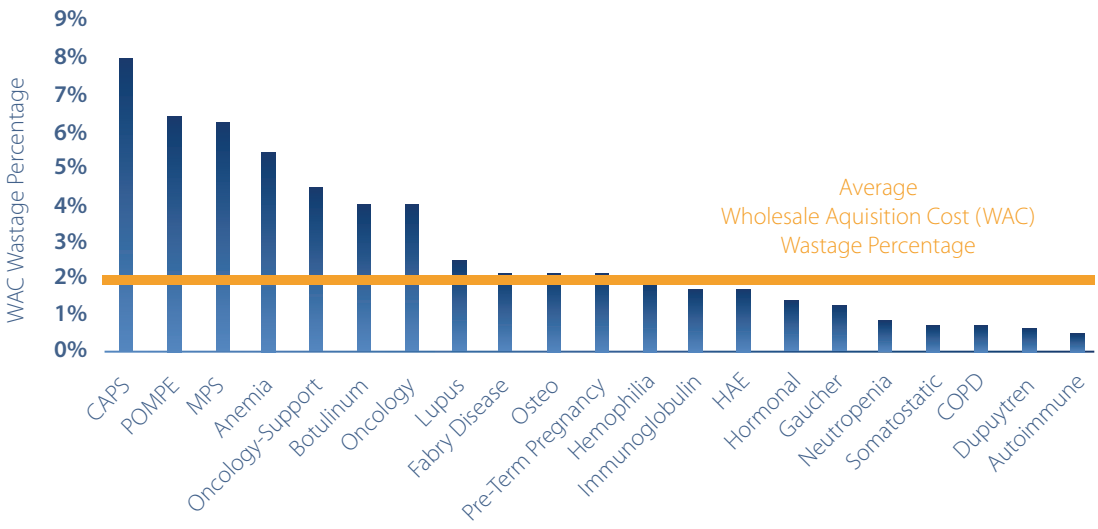

Figure 5: Wastage percent within select therapeutic classes

What is the Size and Scope of the Drug Wastage Challenge?

Wastage reflects a significant source of additional cost beyond the administered component of the drug. In a wastage claim analysis conducted by RJ Health, we found that wastage contributed an additional *two percent, or $0.40 PMPM,* in total spend across all therapeutic classes under the medical benefit. Within individual therapeutic classes the rate of wastage could be significantly higher (Figure 5).

At the drug level the amount of wastage can vary significantly, Figure 6 illustrates the average wholesale acquisition cost (WAC) wastage per claim for the top specialty drugs within our analysis. Within these specialty drugs there are several hemophilia products which represent optimal opportunities for wastage management as multiple vial strengths are typically mixed to get as close as possible to the prescribed dose. For example, Eloctate (J7205) is available in 10 different strength vials. In our analysis we determined that Eloctate had approximately $1,200 in per claim cost associated with wastage that could have been minimized through optimal vial strength selection. *Total wastage with Eloctate represented 18 percent of additional cost* to the health care system within the drugs total spend.

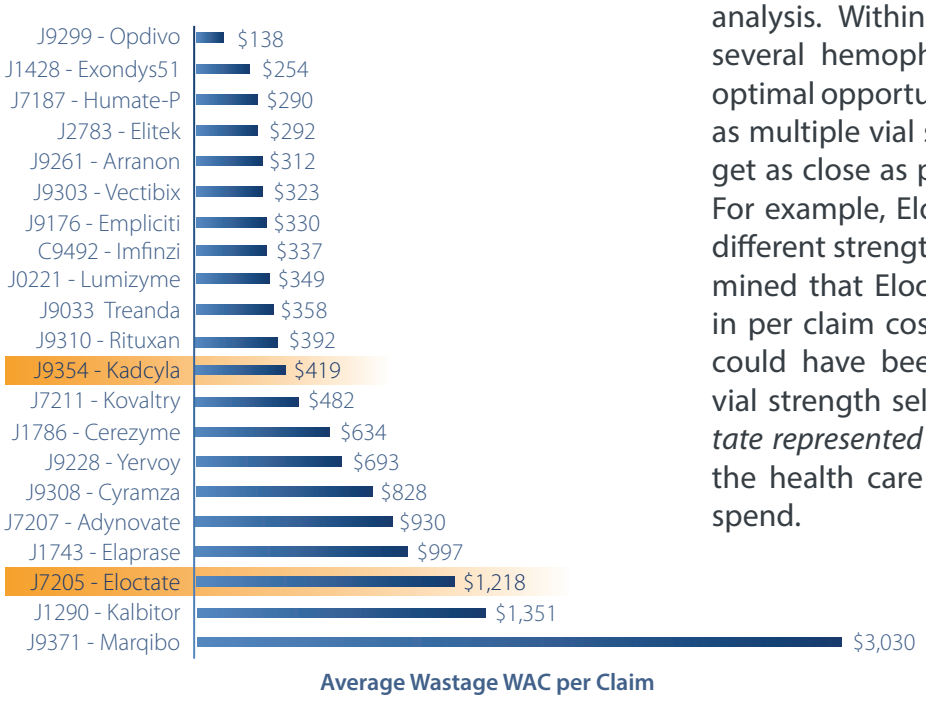

Figure 6: Top specialty drugs with wastage per claim

Who Does Drug Wastage Impact?

Drug wastage has potential cost ramifications to all parties within healthcare delivery and payment systems. From the patient's perspective, wastage results in an increased amount of the overall cost of therapy. A patient with a coinsurance could have a significantly higher amount to pay. Also, consistently, inefficient drug billing for high cost drugs within a small employer group could result in substantial premium increases. Health care professionals and hospitals could have a significant financial impact from not implementing a wastage optimization program. CMS and many health plans have policies in place to mandate optimal wastage billing and these are often subject to audit. Failure by an organization to follow wastage policies could result in penalties for overpayments. From the health plan's perspective, optimal wastage billing is a requirement in their fiduciary responsibility to optimize overall medical spend. Excessive payment for high cost drugs with significant wastage, results in an overall spend increase and downstream impacts to both health care professionals and patients.

How Can Drug Wastage be Addressed?

Addressing drug wastage can be approached from multiple angles. The first would be through policies and procedures and the second would include a layering of tools and services to streamline the process and empower health care professionals. See some approaches below:

1. Stricter wastage reimbursement policies through the usage of appropriate wastage

Drugs must be delivered and billed using the most appropriate size vial, or combination of vials, to deliver the administered dose. CMS has implemented policies in support of appropriate wastage and many health plans have followed suite. The following example provides a comparison of drug waste when there is a substantial difference between available combinations of vials used to deliver the administered dose (Figure 7):

Code J9035: Bevacizumab 10 mg / unit (Avastin ®)				
Prescribed Dose	**Amount Administered**	**Dosage Forms and Strengths**	**Inappropriate Combination**	**Appropriate Combination**
10 mg / kg / 2 weeks *(86 kg patient)*	860 mg	100 mg / 4 mL (Single-Use Vial)		(1) 100 mg vial
		400 mg / 16 mL (Single-Use Vial)	(3) 400 mg vials	+ (2) 400 mg vials
			1200 mg -860 mg dose	900 mg -860 mg dose
			340 mg	**40 mg**
		Total Wastage:	**$3200**	**$318**

(Cont' d on p. 7)

2. Rounding dose down within 10%

Some payors have successfully piloted drug wastage reduction programs by requiring authorization for a targeted drug list and evaluating whether rounding a dose down within 10% of a requested dose will allow for more efficient vial size. In a study conducted by Vandyke et al a total of 6,216 doses of cancer drugs were evaluated for dose rounding. The study concluded that *dose rounding resulted in $200,000 in cost avoidance*.[4] This approach is limited to a handful of drugs where dose rounding has been shown to not have an adverse effect on the overall patient outcome. These products are typically biologics which have a wide therapeutic range. The Hematology/Oncology Pharmacy Association recommended several drugs which could be rounded within 10% of the dose to a lower vial size (Table 1) [2]. In addition, this approach is site of care dependent and requires clinical evaluation of the patient prior to adjustment of dose.

Generic Name	Brand Name	HCPCS
Ado-trastuzumab	Kadcyla®	J9354
Bevacizumab	Avastin®	J9035
Brentuximab vedotin	Adcetris®	J9042
Cetuximab	Erbitux®	J9055
Ipilimumab	Yervoy®	J9228
Rituximab	Rituxan®	J9312
Trastuzumab	Herceptin®	J9355
Ziv-Aflibercept	Zaltrap®	J9400

Table 1: Drug candidates for dose rounding by up To 10%

Ado-trastuzumab (KADCYLA®), which is available in 100 and 160mg vials, has a normal dose of 3.6 mg per kg. For a 77 kg adult the total dose would be 277mg. Figure 8 demonstrates three options in determining the most cost effective dose based on rounding and vial size selection.

3. Schedule multiple patients on the same day to accommodate single-dose vial sharing

This approach requires that the site of care is appropriately set up to handle the usage of single-dose vials for multiple patients within an aseptic environment (clean room) to ensure that bacterial contamination does not occur. In addition, there is a need to use closed-system transfer devices to preserve medication for repeat use. The benefit of this approach was presented by the University of North Carolina Cancer Hospital, where it had been estimated that *wastage was reduced by 94%*, which translated into $39 million in savings. To achieve these savings, they applied the closed-system transfer devices to the 19 most commonly used chemotherapy agents.[3]

Figure 7: Examples of inappropriate and appropriate vial combinations for Bevaclizumab 10mg/unit (Avastin®)

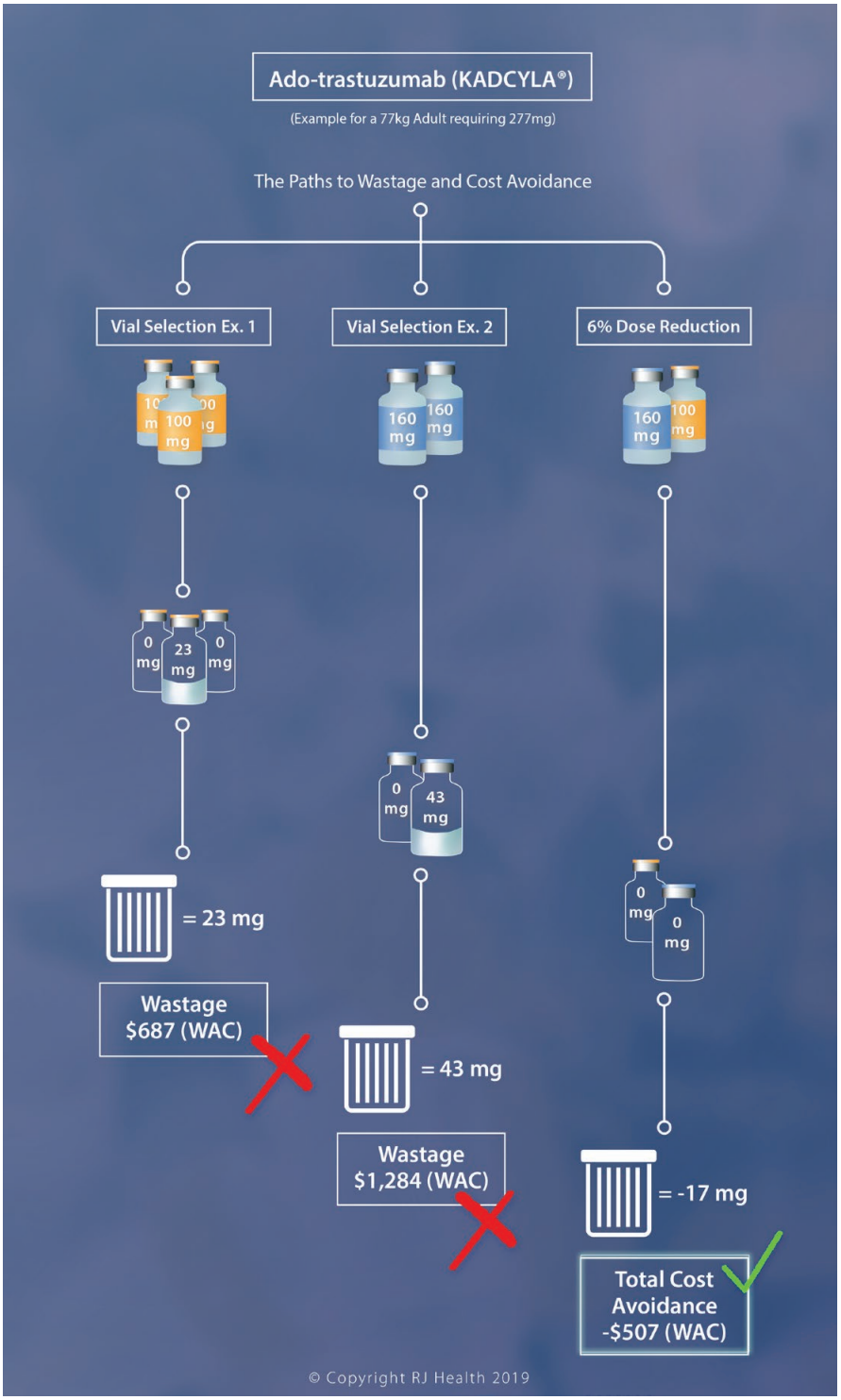

Figure 8: Dose optimization and reduction by 10% or less. Example for a 77kg Adult requiring 277mg of Ado-trastuzumab (KADCYLA®)

Conclusion

To maximize the adoption of one or more of these approaches, organizations will need to consider education to providers and provide supportive tools to manage wastage. Health care professionals and staff within health plans often struggle to implement wastage policies because the required drug-unit mappings and calculations can be complex at times. From a provider perspective, our analysis consistently demonstrates that provider offices lack the knowledge and tools to support the decision making of the appropriate selection of the vials to minimize wastage and ensure accurate billing. From the health plan's perspective, the lack of automation and tools to properly evaluate claims results in inefficient and subpar claim audits for wastage policy compliance. **An end-to-end process in collaboration with the providers is key to the mitigation of drug wastage issue.**

RJ Health proposes a comprehensive wastage solution: One that empowers and provides health care professional offices with the tools to properly ascertain the information that needs to be entered into the claim submission and then automated tools to help health plans quickly validate and process the claim with accuracy and minimal staffing. Through the implementation of one or more of the solutions we propose, wastage reduction and health care delivery optimization can be improved that impacts patients, health care professionals, and health insurance companies.

To learn how you can work with RJ Health to implement or optimize you wastage process today with our end to end solution, please contact us at **(860)563-1223** or info@rjhealth.com.

RJ Health is the market leader in the delivery of data, applications, and analytic solutions to address the clinical management and reimbursement of health care provider administered drugs. We provide scalable industry standard pricing, coding, dosing, weight, age, and diagnosis data & analyses to pharmacy, medical, market access, claims, billing, finance, and network management clientele. Over 85% of the healthcare industry relies on RJ Health to ensure transparency between manufacturer, payor, provider, pharmacies and their respective solution vendors (PBMs, Payment Integrity, Revenue Cycle, EHR, and others).

About the Authors

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Todd Cooperman is Senior Vice President, Clinical Insights and Analytics at RJ Health, with a focus on research and development, strategy, and implementation of data-driven products that optimize the usage of drugs, while ensuring optimal patient care. In addition, Todd oversees the development of analytic methodology, implementation, and reporting for our various clients. He has over 20 years of experience in the health care and insurance industry overseeing the operationalization and strategic development of both pharmacy and medical benefit product offerings and IT system solutions, including the development of clinical programs, formulary design, pharmacoeconomic evaluation, and prior authorization.

Todd has a Doctorate in Pharmacy from Northeastern University, and an MBA from the University of Hartford. Todd completed a pharmacy practice residency at Saint Francis Hospital and the University of Connecticut. He is a Registered Pharmacist in the State of Connecticut and is a member of the Academy of Managed Care Pharmacy and International Society for Pharmacoeconomics and Outcomes. In addition, Todd has various certifications in pharmacy regulatory compliance and data science.

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Manoj Kumar is a Senior Vice President of Products and Innovation at RJ Health, where he provides strategic leadership, and direction to develop innovative product solutions across the eco-system of payors, providers, and channel partners to improve efficiency, drug pricing transparency and reduce cost. He has over 20 years of Healthcare experience. Prior to joining RJ Health, Manoj led the Clinical Product Innovation Team at OptumRx/United Healthcare for six years, where he launched various market differentiator products such as Medication Adherence, Opioid Management and the Disease Management portfolio. Before Optum, he was with Medco Health (now Express Scripts) as Head of Process Improvement for Physician and Provider Advocacy.

Manoj has a MBA from Fairleigh Dickenson University, NJ and a BS in Computer Science, in addition to various certifications such as six-sigma black belt, PMP and CPHIMS.

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